

US3222117 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:02:02

All time stamps listed in this document are displayed in GMT

US3222117

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 16:10:59

Generated On: 09 Jun 2021 16:02:02

[Participant ID](#)

US3222117

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

US3222117

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 12 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) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Date of Informed Consent (*dd MMM yyyy*) 12 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

US3222117

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Condition	DIABETES TYPE II
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1991
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1991
Start Year (derived)	1991
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	JAN 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) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Condition	COPD
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Condition	DIABETIC NEUROPATHY - (HANDS AND FEET) BILATERAL, SENSORY
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Condition	RESTLESS LEG SYNDROME - BILATERAL
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	_____
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Condition	ALLERGIES - SEASONAL
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:55 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 15:55
Height (<i>xxx.x</i>)	172.7 cm
Weight (<i>xxx.x</i>)	136.0 kg
BMI (<i>xxx.x</i>)	45.59889 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

12 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) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

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 RETIRED

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) 19 Feb 2021 16:11:01

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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)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 12 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) 26 Apr 2021 13:48:13

Generated On: 09 Jun 2021 16:02:02

What was the date of randomization? (dd MMM yyyy) 12 AUG 2020

What was the participant's randomization number? 186009

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) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

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) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:00 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 16:00
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	75 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	62 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	17:20 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 17:20
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	69 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3222117

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

12 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

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) 12 AUG 2020

What was the treatment time? (00:00-23:59) 16:49 (24 HR)

Treatment Date and Time (derived) 12 AUG 2020 16:49

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) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	12 AUG 2020
Collection time (<i>00:00-23:59</i>)	16:40 (24 HR)
Collection date and time (derived)	12 AUG 2020 16:40

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Collection date (<i>dd MMM yyyy</i>)			12 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:42	12 AUG 2020 16:42
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.4 °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 12 AUG 2020 17:25

PC Open Date & Time 12 AUG 2020 17:09

PC Close Date & Time 12 AUG 2020 19:39

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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 95.8 °F

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

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

PC Time Stamp	13 AUG 2020 06:44
PC Open Date & Time	12 AUG 2020 20:34
PC Close Date & Time	13 AUG 2020 11:59

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

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

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred _____
To **PREVENT** pain or fever from occurring _____
PC Time Stamp _____
PC Open Date & Time 13 AUG 2020 12:00
PC Close Date & Time 14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.9 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	14 AUG 2020 12:04
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.7 °F

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

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

PC Time Stamp 15 AUG 2020 14:30

PC Open Date & Time 15 AUG 2020 12:00

PC Close Date & Time 16 AUG 2020 11:59

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 5

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes
No

Please record your **TEMPERATURE** in °F _____
Was any **MEDICATION TAKEN** today for pain or fever? Yes
No

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred _____
To **PREVENT** pain or fever from occurring _____
PC Time Stamp _____
PC Open Date & Time 16 AUG 2020 12:00
PC Close Date & Time 17 AUG 2020 11:59

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

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

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred
To **PREVENT** pain or fever from occurring
PC Time Stamp
PC Open Date & Time 17 AUG 2020 12:00
PC Close Date & Time 18 AUG 2020 11:59

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	18 AUG 2020 20:18
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp	12 AUG 2020 17:26
PC Open Date & Time	12 AUG 2020 17:09
PC Close Date & Time	12 AUG 2020 19:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

13 AUG 2020 06:45

PC Open Date & Time

12 AUG 2020 20:34

PC Close Date & Time

13 AUG 2020 11:59

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 3

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	14 AUG 2020 12:04
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 4

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

15 AUG 2020 14:31

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 5

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 6

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 7

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

18 AUG 2020 20:18

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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

No

Yes

PC Time stamp	12 AUG 2020 17:27
PC Open Date & Time	12 AUG 2020 17:09
PC Close Date & Time	12 AUG 2020 19:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

No
Yes

PC Time stamp	13 AUG 2020 06:46
PC Open Date & Time	12 AUG 2020 20:34
PC Close Date & Time	13 AUG 2020 11:59

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

Yes

PC Time stamp

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

	Yes <input type="checkbox"/>
PC Time stamp	14 AUG 2020 12:05
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

Yes

PC Time stamp	15 AUG 2020 14:31
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

Yes

PC Time stamp

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

Yes

PC Time stamp

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 19 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3222117

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222117

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 26 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3222117

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222117

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 2 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3222117

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222117

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:11:02

Generated On: 09 Jun 2021 16:02:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	VISIT2

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 16:11:02

Generated On: 09 Jun 2021 16:02:02

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:19 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 10:19
Temperature (<i>xxx.x</i>)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	64 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 16:11:02

Generated On: 09 Jun 2021 16:02:02

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	11:49 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 11:49
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3222117

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:11:02

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3222117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 11:16 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 11:16

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

US3222117

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:11:02

Generated On: 09 Jun 2021 16:02:02

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 10 SEP 2020

Collection time (*00:00-23:59*) 10:32 (24 HR)

Collection date and time (derived) 10 SEP 2020 10:32

US3222117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Collection date (<i>dd MMM yyyy</i>)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:35	10 SEP 2020 10:35
Nasopharyngeal Swab 2	No		

US3222117

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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 97.8 °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 10 SEP 2020 13:51

PC Open Date & Time 10 SEP 2020 11:36

PC Close Date & Time 10 SEP 2020 14:06

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

10 SEP 2020 15:01

PC Close Date & Time

11 SEP 2020 11:59

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.6 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	11 SEP 2020 21:26
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	12 SEP 2020 18:15
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes
No

Please record your **TEMPERATURE** in °F _____
Was any **MEDICATION TAKEN** today for pain or fever? Yes
No

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred _____
To **PREVENT** pain or fever from occurring _____
PC Time Stamp _____
PC Open Date & Time 13 SEP 2020 12:00
PC Close Date & Time 14 SEP 2020 11:59

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE in °F**
Was any **MEDICATION TAKEN today for pain or fever?** Yes No

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred
To **PREVENT** pain or fever from occurring
PC Time Stamp
PC Open Date & Time 14 SEP 2020 12:00
PC Close Date & Time 15 SEP 2020 11:59

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.2 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	15 SEP 2020 13:22
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

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 _____

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

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

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

To **PREVENT** pain or fever from occurring _____

PC Time Stamp _____

PC Open Date & Time 16 SEP 2020 12:00

PC Close Date & Time 17 SEP 2020 11:59

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp	10 SEP 2020 13:52
PC Open Date & Time	10 SEP 2020 11:36
PC Close Date & Time	10 SEP 2020 14:06

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

10 SEP 2020 15:01

PC Close Date & Time

11 SEP 2020 11:59

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 2

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	11 SEP 2020 21:27
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 3

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

12 SEP 2020 18:16

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 4

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 5

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 6

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

15 SEP 2020 13:22

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 7

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms? No
Yes

PC Time stamp	10 SEP 2020 13:52
PC Open Date & Time	10 SEP 2020 11:36
PC Close Date & Time	10 SEP 2020 14:06

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

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

No

Yes

PC Time stamp

PC Open Date & Time

10 SEP 2020 15:01

PC Close Date & Time

11 SEP 2020 11:59

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

	Yes <input type="checkbox"/>
PC Time stamp	12 SEP 2020 18:16
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

Yes

PC Time stamp

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

Yes

PC Time stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

	Yes <input type="checkbox"/>
PC Time stamp	15 SEP 2020 13:23
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

Yes

PC Time stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3222117

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 17 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3222117

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222117

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3222117

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222117

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 1 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3222117

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222117

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:11:02

Generated On: 09 Jun 2021 16:02:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3222117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:11:02

Generated On: 09 Jun 2021 16:02:02

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) _____

US3222117

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:11:02

Generated On: 09 Jun 2021 16:02:02

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.

US3222117

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:11:02

Generated On: 09 Jun 2021 16:02:02

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 7 OCT 2020

Collection time (*00:00-23:59*) 10:45 (24 HR)

Collection date and time (derived) 7 OCT 2020 10:45

US3222117

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:11:02

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 16 OCT 2020 14:56:04

Patient Cloud Open Date & Time 12 OCT 2020 00:01

Patient Cloud Close Date & Time 16 OCT 2020 23:59

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 19 OCT 2020 10:24:06

Patient Cloud Open Date & Time 19 OCT 2020 00:01

Patient Cloud Close Date & Time 23 OCT 2020 23:59

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 78

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

No

Yes

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

No

Yes

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

Date and time of submission 26 OCT 2020 10:00:16

Patient Cloud Open Date & Time 26 OCT 2020 00:01

Patient Cloud Close Date & Time 30 OCT 2020 23:59

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 09 NOV 2020 09:01:34

Patient Cloud Open Date & Time 09 NOV 2020 00:01

Patient Cloud Close Date & Time 13 NOV 2020 23:59

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	True
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	False
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	True
New loss of smell	True
Sore throat	False
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	16 NOV 2020 08:46:50
Patient Cloud Open Date & Time	16 NOV 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	124 of 3325

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

20 NOV 2020 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 103

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

No

Yes

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

No

Yes

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

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

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

Date and time of submission 20 NOV 2020 07:35:32

Patient Cloud Open Date & Time 20 NOV 2020 00:01

Patient Cloud Close Date & Time 24 NOV 2020 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 07:48:18
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	06 DEC 2020 10:18:19
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	11 DEC 2020 08:30:54
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	19 DEC 2020 09:23:49
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	25 DEC 2020 08:39:06
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	True
Fatigue	False
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	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	01 JAN 2021 03:07:54
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 04:02:06
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	15 JAN 2021 05:13:54
Patient Cloud Open Date & Time	15 JAN 2021 00:01

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 166

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

No

Yes

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

No

Yes

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

Date and time of submission 22 JAN 2021 09:39:10

Patient Cloud Open Date & Time 22 JAN 2021 00:01

Patient Cloud Close Date & Time 26 JAN 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 173

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

No

Yes

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

No

Yes

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

Date and time of submission 29 JAN 2021 06:51:48

Patient Cloud Open Date & Time 29 JAN 2021 00:01

Patient Cloud Close Date & Time 02 FEB 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 FEB 2021 10:34:40
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 11:03:51
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 07:58:24
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 FEB 2021 06:30:26
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 208

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

No

Yes

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

No

Yes

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

Date and time of submission 05 MAR 2021 05:56:53

Patient Cloud Open Date & Time 05 MAR 2021 00:01

Patient Cloud Close Date & Time 09 MAR 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 MAR 2021 06:56:11
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 222

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

No

Yes

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

No

Yes

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

Date and time of submission 19 MAR 2021 06:15:43

Patient Cloud Open Date & Time 19 MAR 2021 00:01

Patient Cloud Close Date & Time 23 MAR 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 MAR 2021 06:11:51
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 236

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

No

Yes

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

No

Yes

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

Date and time of submission 02 APR 2021 09:42:16

Patient Cloud Open Date & Time 02 APR 2021 00:01

Patient Cloud Close Date & Time 06 APR 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 17:38:40
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 APR 2021 09:37:39
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 257

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

No

Yes

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

No

Yes

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

Date and time of submission 23 APR 2021 07:39:52

Patient Cloud Open Date & Time 23 APR 2021 00:01

Patient Cloud Close Date & Time 27 APR 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 APR 2021 06:25:29
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 271

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 285

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission	
Patient Cloud Open Date & Time	21 MAY 2021 00:01
Patient Cloud Close Date & Time	25 MAY 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission	
Patient Cloud Open Date & Time	28 MAY 2021 00:01
Patient Cloud Close Date & Time	01 JUN 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 299

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission	
Patient Cloud Open Date & Time	04 JUN 2021 00:01
Patient Cloud Close Date & Time	08 JUN 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 306

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 320

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

Patient Cloud Open Date & Time	02 JUL 2021 00:01
Patient Cloud Close Date & Time	06 JUL 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 341

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 348

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 355

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission	
Patient Cloud Open Date & Time	06 AUG 2021 00:01
Patient Cloud Close Date & Time	10 AUG 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#) 17 AUG 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 383

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#) 31 AUG 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 390

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#) 07 SEP 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 404

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	21 SEP 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 411

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

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

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

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

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

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

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission	
Patient Cloud Open Date & Time	24 SEP 2021 00:01
Patient Cloud Close Date & Time	28 SEP 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 418

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 19 OCT 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 439

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 26 OCT 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 453

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 460

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2021 00:01
Patient Cloud Close Date & Time	16 NOV 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 467

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 474

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 481

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 495

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 28 DEC 2021 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#) 04 JAN 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 544

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#) 08 FEB 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 558

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 572

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 586

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 600

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 607

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 614

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission	
Patient Cloud Open Date & Time	15 APR 2022 00:01
Patient Cloud Close Date & Time	19 APR 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 621

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission	
Patient Cloud Open Date & Time	22 APR 2022 00:01
Patient Cloud Close Date & Time	26 APR 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 628

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 635

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 642

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#) 17 MAY 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 649

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 656

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 663

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#) 07 JUN 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 670

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

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

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

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

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

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

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 677

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 691

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

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

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

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

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

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

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 698

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 719

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

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

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

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

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

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

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 733

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#) 16 AUG 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 740

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 747

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

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

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

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

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

- Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 768

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission	
Patient Cloud Open Date & Time	16 SEP 2022 00:01
Patient Cloud Close Date & Time	20 SEP 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 775

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 782

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 789

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#) 11 OCT 2022 23:59

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

DAY 796

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

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#) 18 OCT 2022 23:59

US3222117

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:02:02

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 13:00:39

US3222117

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 4 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3222117

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222117

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 09 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3222117

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222117

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 08 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3222117

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222117

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 7 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3222117

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222117

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 13:48:13

Generated On: 09 Jun 2021 16:02:02

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 25 FEB 2021

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

Folder OID VISIT4

US3222117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 13:48:13

Generated On: 09 Jun 2021 16:02:02

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) _____

US3222117

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 13:48:13

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3222117

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 13:48:13

Generated On: 09 Jun 2021 16:02:02

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 25 FEB 2021

Collection time (*00:00-23:59*) 11:15 (24 HR)

Collection date and time (derived) 25 FEB 2021 11:15

US3222117

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 13:48:13

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222117

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 07 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3222117

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3222117

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) _____

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

Comments _____

If Contact Not Made, please provide Comments _____

US3222117

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Feb 2021 16:11:00

Generated On: 09 Jun 2021 16:02:02

Date of Contact	17 NOV 2020
Time of Contact	08:50
Date and Time of Contact (derived)	17 NOV 2020 08:50
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/> Clinical Visit - Unscheduled <input type="radio"/> Safety Call <input type="radio"/> Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/> No <input type="radio"/>

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

Date	13 NOV 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	100.4 F
-------------	---------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	100.4 F	
Chills	None <input type="checkbox"/>	
	Mild <input type="checkbox"/>	
	Moderate <input checked="" type="checkbox"/>	
	Severe <input type="checkbox"/>	
	Not Done <input type="checkbox"/>	
Cough	None <input checked="" type="checkbox"/>	
	Mild <input type="checkbox"/>	
	Moderate <input type="checkbox"/>	
	Severe <input type="checkbox"/>	
	Not Done <input type="checkbox"/>	
Shortness of Breath	None <input checked="" type="checkbox"/>	
	Mild <input type="checkbox"/>	
	Moderate <input type="checkbox"/>	
	Severe <input type="checkbox"/>	
	Not Done <input type="checkbox"/>	
Difficulty Breathing	None <input checked="" type="checkbox"/>	
	Mild <input type="checkbox"/>	
	Moderate <input type="checkbox"/>	
	Severe <input type="checkbox"/>	

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

Date	15 NOV 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	100.4 F
-------------	---------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

Date 16 NOV 2020

Assessment Not Done False

O2 Saturation ND - Not Done

O2 Saturation Units %

Temperature 100.4 F

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

Date 17 NOV 2020

Assessment Not Done False

O2 Saturation 98 %

O2 Saturation Units %

Temperature 36.7 C

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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 17 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

Date	18 NOV 2020
------	-------------

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

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

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

Temperature	98.5 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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 17 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

Date	19 NOV 2020
------	-------------

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

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

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

Temperature	98.6 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

Date	20 NOV 2020
Assessment Not Done	False
O2 Saturation	94 %
O2 Saturation Units	%
Temperature	98.3 F

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

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

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

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

Date	21 NOV 2020
------	-------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	98.3 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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 17 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

Date 22 NOV 2020

Assessment Not Done False

O2 Saturation 97 %

O2 Saturation Units %

Temperature 98.3 F

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

Date	23 NOV 2020
------	-------------

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

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

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

Temperature	97.0 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

Date 24 NOV 2020

Assessment Not Done False

O2 Saturation 95 %

O2 Saturation Units %

Temperature 97.6 F

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

Date	25 NOV 2020
------	-------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	98.0 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

Date	26 NOV 2020
------	-------------

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

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

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

Temperature	98.1 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

Date	27 NOV 2020
------	-------------

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

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

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

Temperature	98.6 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

Date	28 NOV 2020
------	-------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	98.0 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

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

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

Date	29 NOV 2020
------	-------------

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

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

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

Temperature	97.9 F
-------------	--------

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

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 30 NOV 2020

Assessment Not Done False

O2 Saturation 94 %

O2 Saturation Units %

Temperature 98.1 F

Chills

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Cough

None	<input type="radio"/>
Mild	<input type="radio"/>
Moderate	<input checked="" type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Shortness of Breath

None	<input type="radio"/>
Mild	<input type="radio"/>
Moderate	<input checked="" type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Difficulty Breathing

None	<input type="radio"/>
Mild	<input type="radio"/>
Moderate	<input checked="" type="radio"/>
Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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 17 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 01 DEC 2020

Assessment Not Done False

O2 Saturation 97 %

O2 Saturation Units %

Temperature 98.3 F

Chills

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Cough

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Shortness of Breath

None	<input type="radio"/>
Mild	<input type="radio"/>
Moderate	<input checked="" type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Difficulty Breathing

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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 17 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input checked="" type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	2 DEC 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	95 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.6 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input checked="" type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 3 DEC 2020

Assessment Not Done False

O2 Saturation 95 %

O2 Saturation Units %

Temperature 98.1 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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input checked="" type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	4 DEC 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	94 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98 F
-------------	------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	5 DEC 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	95 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	99.3 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input checked="" type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date 6 DEC 2020

Assessment Not Done False

O2 Saturation 95 %

O2 Saturation Units %

Temperature 98.1 F

Chills

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Cough

None	<input type="radio"/>
Mild	<input type="radio"/>
Moderate	<input checked="" type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Shortness of Breath

None	<input type="radio"/>
Mild	<input type="radio"/>
Moderate	<input checked="" type="radio"/>
Severe	<input type="radio"/>
Not Done	<input type="radio"/>

Difficulty Breathing

None	<input checked="" type="radio"/>
Mild	<input type="radio"/>
Moderate	<input type="radio"/>
Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input checked="" type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	7 DEC 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	95 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.7 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input checked="" type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	8 DEC 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	95 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	99.7 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input checked="" type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	9 DEC 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	94 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	99 F
-------------	------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input checked="" type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	10 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	94 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.8 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input checked="" type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	11 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	94 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.9 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input checked="" type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	12 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	92 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.7 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Not Done <input type="radio"/>
Fatigue	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input checked="" type="checkbox"/>
Day 32	<input type="checkbox"/>

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	13 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	95 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.7 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

	Not Done <input type="radio"/>
Fatigue	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Muscle Aches (Myalgia)	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Body Aches	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
Headache	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Taste	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>
New Loss of Smell	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Data signed: (b) (4) 05 Mar 2021 21:08:13

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 19 Feb 2021 16:11:00

Generated On: 09 Jun 2021 16:02:02

Date of Visit 17 NOV 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes
No

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes
No

Date of Test 17 NOV 2020

Type of Test Performed Nasopharyngeal Swab
Nasal Swab
Saliva Test
Other

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes
No

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes
No

COVID-19 Positive (CSA Programming Field Only) 1

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 22:12:50

Generated On: 09 Jun 2021 16:02:02

Did the subject have Respiratory Rates \geq 30 per Minute? Yes
No

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate \geq 125 beats per minute? Yes
No

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ \leq 93% on room air at sea level? Yes
No

If Yes, provide:

Start Date 12 DEC 2020

End Date 13 DEC 2020

Oxygen Saturation 92 %

Did the subject have PaO₂/FIO₂ Ratio $<$ 300 mm Hg? Yes
No

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes
No

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes
No

Start Date _____

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 22:12:50

Generated On: 09 Jun 2021 16:02:02

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes
No

Start Date _____

End Date _____

Non-Invasive Ventilation? Yes
No

Start Date _____

End Date _____

Mechanical Ventilation? Yes
No

Start Date _____

End Date _____

ECMO? Yes
No

Start Date _____

End Date _____

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes
No

Start Date _____

End Date _____

Evidence of Shock Requires Vasopressors Yes
No

Start Date _____

End Date _____

Acute Renal Dysfunction? Yes
No

Start Date _____

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 22:12:50

Generated On: 09 Jun 2021 16:02:02

Hepatic Dysfunction? Yes
No

Start Date _____

Neurologic Dysfunction? Yes
No

Start Date _____

Evidence of Pneumonia:

Clinical Evidence Yes
No

Date of Assessment _____

Radiographical Evidence Yes
No

Date of Assessment _____

Admission to an intensive care unit due to SARS-CoV-2 Yes
No

Start Date _____

End Date _____

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 19 Feb 2021 16:11:00

Generated On: 09 Jun 2021 16:02:02

[Generate Next COVID-19 Assessment](#)

Yes

No

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	19 NOV 2020
Day 5	Yes	21 NOV 2020
Day 7	Yes	23 NOV 2020
Day 9	Yes	25 NOV 2020
Day 14	Yes	30 NOV 2020
Day 21	Yes	07 DEC 2020
Day 28	Yes	17 DEC 2020

US3222117

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:11:00

Generated On: 09 Jun 2021 16:02:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:11:00

Generated On: 09 Jun 2021 16:02:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	09:18 (24 HR)
Vital Signs Date and Time (derived)	17 NOV 2020 09:18
Height (<i>xxx.x</i>)	172.7 cm
Weight (<i>xxx.x</i>)	135.6 kg
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	163 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3222117

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:11:00

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

17 NOV 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3222117

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 19 Feb 2021 16:11:00

Generated On: 09 Jun 2021 16:02:02

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Yes

No

NA (COVID-19 Negative)

Date of Collection

17 NOV 2020

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:11:00

Generated On: 09 Jun 2021 16:02:02

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 15:49:54

Generated On: 09 Jun 2021 16:02:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	13:45 (24 HR)
Vital Signs Date and Time (derived)	17 DEC 2020 13:45
Height (<i>xxx.x</i>)	172.7 cm
Weight (<i>xxx.x</i>)	137.1 kg
Temperature (<i>xxx.x</i>)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	70 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	178 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:11:00

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

17 DEC 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 19 Feb 2021 16:11:00

Generated On: 09 Jun 2021 16:02:02

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

Yes

No

NA (COVID-19 Negative)

Date of Collection

17 DEC 2020

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:11:00

Generated On: 09 Jun 2021 16:02:02

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 24 JAN 2021

Was visit performed at the participant's home or at the clinic? Home
Clinic

Folder OID UNBLND_DECIDE

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

Date of updated informed consent (*dd MMM yyyy*) 24 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes
No

Under what version of the Protocol was the Participant unblinded? Amendment 5
Amendment 6 or later

Date of unblinding (*dd MMM yyyy*) 24 JAN 2021

Participant randomization assignment mRNA-1273
Placebo

Actual Dose 1 mRNA-1273
Placebo
Not Administered

Actual Dose 2 mRNA-1273
Placebo
Not Administered

Will participant receive mRNA-1273? Yes
No

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 16:11:00

Generated On: 09 Jun 2021 16:02:02

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 24 JAN 2021

Collection time (*00:00-23:59*) 10:31 (24 HR)

Collection date and time (derived) 24 JAN 2021 10:31

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 16:11:00

Generated On: 09 Jun 2021 16:02:02

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 24 JAN 2021

Collection time (*00:00 - 23:59*) 10:33

Collection Date and Time (derived) 24 JAN 2021 10:33

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Unscheduled Visit Assessment**

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Visit Date	9 DEC 2020
------------	------------

Please check all assessments that apply for this visit

Physical Exam	True
---------------	------

Vital Signs	True
-------------	------

Immunogenicity Assessment	False
---------------------------	-------

Pregnancy Test	False
----------------	-------

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Vital Signs**

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	9 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	10:15 (24 HR)
Vital Signs Date and Time (derived)	9 DEC 2020 10:15
Temperature (<i>xxx.x</i>)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	65 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Physical Examination**

Data signed: (b) (4) 19 Feb 2021 16:11:01

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

9 DEC 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3222117

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 16:10:59

Generated On: 09 Jun 2021 16:02:02

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

AEID USA-US104-2020-MRNA-1273-P30
1000021

Adverse event COVID-19.

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) 13 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) 17 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	POSITIVE PCR FOR COVID-19 AND HE'S IS NOW ON TELEMEDICINE CALLS DAILY.
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: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

AEID USA-US104-2020-MRNA-1273-P30
1000024

Adverse event COPD EXACERBATION

Was this a medically-attended AE? Yes
No

Was this a Solicited Adverse Reaction? Yes
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes
No

Start date (dd MMM yyyy) 11 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 15 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 11 DEC 2020

Hospital Discharge Date (dd MMM yyyy) 15 DEC 2020

Admitted to ICU? Yes
No
Unknown

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EAB) (1725)

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US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

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 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

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

I WAS INFORMED OF THE SAE AT 18:02 PM ON 11/DEC/2020. I SPOKE WITH THE PATIENT AND HIS WIFE DROVE HIM TO THE EMERGENCY ROOM AND THEY WILL EVALUATE WHY HE IS SHORT OF BREATH. HE HAS BEEN ON MY TELEMEDICINE CALLS SINCE 17/NOV/2020. I WILL CONTINUE TO CALL HIM EVERY NIGHT, AND HIS DAY 28 IS SCHEDULED FOR 15/DEC/2020. I WILL REQUEST RECORDS AFTER HE IS DISCHARGED.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3222117

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

AEID _____

Adverse event _____

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) _____

Start time (00:00-23:59) _____

AE start date and time (derived) _____

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) _____

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 _____

Life threatening _____

Requires inpatient or prolongation of existing Hospitalization _____

Hospital Admission Date (dd MMM yyyy) _____

Hospital Discharge Date (dd MMM yyyy) _____

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU _____

US3222117

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

Persistent or significant disability or incapacity _____

Congenital anomaly or birth defect _____

Other medically important event _____

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 _____

Concomitant Medication _____

Concomitant Procedure _____

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) _____

Medically Attended AE Derived (CSA Programming Field Only) _____

Admitted to ICU Derived (CSA Programming Field Only) _____

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 16:11:00

Generated On: 09 Jun 2021 16:02:02

Were any prior/concomitant medications and/or vaccinations taken?

Yes

No

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Name of Medication LANTUS

Prophylaxis Yes
No

Indication DIABETES

Dose per administration 40

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2013

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

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Name of Medication NOVOLOG

Prophylaxis Yes
No

Indication DIABETES

Dose per administration SLIDING SCALE

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) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2013

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) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Name of Medication LASIX

Prophylaxis Yes
No

Indication COPD

Dose per administration UNK

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

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2017

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

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Name of Medication SINGULAIR

Prophylaxis Yes
No

Indication ALLERGIES - SEASONAL

Dose per administration 10

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2002

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

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Name of Medication BISOPROLOL

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2004

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

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Name of Medication PLAVIX

Prophylaxis Yes
No

Indication BLOOD CLOT PREVENTION

Dose per administration 75

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2016

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

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Name of Medication LISINOPRIL

Prophylaxis Yes
No

Indication HYPERTENSION

Dose per administration 20

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 1991

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

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Name of Medication SPIRONOLACTONE

Prophylaxis Yes
No

Indication HYPERTENSION

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2016

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

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Name of Medication ADVAIR

Prophylaxis Yes
No

Indication COPD

Dose per administration 250/50

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify MCGS

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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US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2002

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

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Name of Medication ASPIRIN

Prophylaxis Yes
No

Indication CARDIAC SUPPLEMENT

Dose per administration 81

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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US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 1980

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

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Name of Medication GABAPENTIN

Prophylaxis Yes
No

Indication DIABETIC NEUROPATHY -
(HANDS AND FEET)

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

496 of 3325

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Name of Medication ROSUVASTATIN

Prophylaxis Yes
No

Indication HYPERCHOLESTERLEMIA

Dose per administration 20

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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US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2000

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

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Name of Medication PRAMIPEXOLE

Prophylaxis Yes
No

Indication RESTLESS LEG SYNDROME

Dose per administration 1.5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2015

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

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Name of Medication TRAZODONE

Prophylaxis Yes
No

Indication INSOMNIA

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2015

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

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Name of Medication ACETAMINOPHEN-HYDROCOD
ONE

Prophylaxis Yes
No

Indication CHEST PAIN/ CHRONIC
OBSTRUCTIVE PULMONARY
DISEASE

Dose per administration 325-7.5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

Frequency once daily
twice daily
three times daily
four times daily
every other day
every week
every month
as needed
once
unknown
other

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

- Transdermal
- 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) 11 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 12 DEC 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

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Name of Medication CEFUROXIME

Prophylaxis Yes
No

Indication BACTERIAL INFECTION

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

BID FOR 7 DAYS

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 11 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 17 DEC 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

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Name of Medication PREDNISONE

Prophylaxis Yes
No

Indication SHORTNESS OF BREATH

Dose per administration 20

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

BID X 3 DAYS

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 25 Mar 2021 17:16:17

Generated On: 09 Jun 2021 16:02:02

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 11 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 13 DEC 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

US3222117

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 16:11:00

Generated On: 09 Jun 2021 16:02:02

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3222117

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:02:02

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

US3222117

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:02:02

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify)

SAE (specify)

Complete

Death

Lost To Follow-up

Physician decision (specify)

Pregnancy

Protocol deviation (specify)

Study Terminated By Sponsor

Withdrawal of consent by
participant (specify)

Other

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event

Unknown

Other

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes

No

Unknown

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

SAEID	USA-US104-2020-MRNA-1273-P30 1000021
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

SAEID	USA-US104-2020-MRNA-1273-P301000021
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	01/DEC/2020 16:34
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

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

SAEID	USA-US104-2020-MRNA-1273-P301000021
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	09/FEB/2021 12:01
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

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

SAEID	USA-US104-2020-MRNA-1273-P30 1000024
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

SAEID	USA-US104-2020-MRNA-1273-P301000024
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	14/DEC/2020 10:23
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

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

SAEID	USA-US104-2020-MRNA-1273-P301000024
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	27/JAN/2021 08:30
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

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

SAEID	USA-US104-2020-MRNA-1273-P301000024
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/FEB/2021 12:04
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

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

SAEID	USA-US104-2020-MRNA-1273-P301000024
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	01/MAR/2021 11:19
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

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 13:48:12

Generated On: 09 Jun 2021 16:02:02

SAEID	USA-US104-2020-MRNA-1273-P301000024
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	13/APR/2021 13:41
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

US3222117 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222117

Form: Participant Creation

Generated On: 09 Jun 2021 16:02:02

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'US3222117'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 20:19:26

US3222117

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:36:35
User entered 'Yes (Y)'	Jennifer Dittman (b) (4) (b) (4)	12 Aug 2020 20:38:26

US3222117

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:36:35
User entered '12 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 20:19:27

US3222117

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:36:35
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4) (b) (4)	12 Aug 2020 20:38:26

US3222117

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered 'SCRN'	System	12 Aug 2020 20:38:26

US3222117

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:36:43
User entered (b) (6) 1954'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 20:19:28

US3222117

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:36:43
User entered '66'	(b) (4), (b) (6)	13 Aug 2020 13:56:15

US3222117

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered 'YEARS'	System	13 Aug 2020 13:56:15

US3222117

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered '66'	System	12 Aug 2020 20:38:38

US3222117

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:36:43
User entered 'Male (M)'	(b) (4), (b) (6)	13 Aug 2020 13:56:15

US3222117

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:36:43
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	13 Aug 2020 13:56:15

US3222117

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:36:43
User entered 'l'	(b) (4), (b) (6)	13 Aug 2020 13:56:15

US3222117

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:36:43
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 13:56:15

US3222117

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:36:43
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 13:56:15

US3222117

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:36:43
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 13:56:15

US3222117

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:36:43
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 13:56:15

US3222117

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:36:43
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 13:56:15

US3222117

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:36:43
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 13:56:15

US3222117

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:36:43
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 13:56:15

US3222117

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:02:02

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:36:43
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 13:56:15

US3222117

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Sep 2020 08:04:49
User entered '12 Aug 2020'	Jennifer Dittman (b) (4) (b) (4)	12 Aug 2020 20:38:38

US3222117

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered 'Aug 2020'	System	12 Aug 2020 20:38:38

US3222117

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered '2020'	System	12 Aug 2020 20:38:38

US3222117

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Sep 2020 08:04:49
User entered 'Amendment 1 (1)'	Jennifer Dittman (b) (4) (b) (4)	12 Aug 2020 20:38:38

US3222117

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Sep 2020 08:04:49
User entered 'Yes (Y)'	Jennifer Dittman (b) (4) (b) (4)	12 Aug 2020 20:38:38

US3222117

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Sep 2020 08:04:49
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	12 Aug 2020 20:38:38

US3222117

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Sep 2020 08:04:49
User entered empty.	Jennifer Dittman (b) (4) (b) (4)	12 Aug 2020 20:38:38

US3222117

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Sep 2020 08:04:49
User entered 'No (N)'	Jennifer Dittman (b) (4) (b) (4)	12 Aug 2020 20:38:38

US3222117

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Sep 2020 08:04:49
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 20:19:27

US3222117

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:02:02

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered '1'	System	12 Aug 2020 20:38:44

US3222117

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:02:02

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	12 Aug 2020 20:38:44

US3222117

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:02:02

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	(b) (4) Jennifer Dittman (b) (4)	12 Aug 2020 20:39:01

US3222117

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment is typically expected. Please review and if applicable add a Con Med or comment for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:40:59
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment is typically expected. Please review and if applicable add a Con Med or comment for no medical treatment. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:23:18
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment is typically expected. Please review and if applicable add a Con Med or comment for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 06:55:22
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 15:50:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 15:50:37
Data point term sent to Coder	System	05 Sep 2020 15:49:46
User entered 'Diabetes Type II'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:49:21

US3222117

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'un UNK 2012' reason for change: Data Entry Error	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:52:30
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	05 Sep 2020 15:50:03
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	05 Sep 2020 15:49:21
User entered empty.	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:49:21

US3222117

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Amber Vasquez (b) (4)	05 Sep 2020 15:52:30
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Amber Vasquez (b) (4)	05 Sep 2020 15:50:03
User entered '0'	(b) (4)	
	Amber Vasquez (b) (4)	05 Sep 2020 15:49:21
	(b) (4)	

US3222117

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	(b) (4) System	05 Sep 2020 15:50:03
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	05 Sep 2020 15:49:21
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:49:21

US3222117

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:49:21

US3222117

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '0' reason for change: Data Entry Error	(b) (4)	05 Sep 2020 15:50:03
User entered '1'	Amber Vasquez (b) (4)	05 Sep 2020 15:49:21
	(b) (4)	

US3222117

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered 'Jan 2012'	System	05 Sep 2020 15:52:30
User entered empty.	System	05 Sep 2020 15:49:21

US3222117

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered '2012'	System	05 Sep 2020 15:52:30
User entered empty.	System	05 Sep 2020 15:49:21

US3222117

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	05 Sep 2020 15:49:21

US3222117

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:02:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	05 Sep 2020 15:49:21

US3222117

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment is typically expected. Please review and if applicable add a Con Med or comment for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:45:45
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment is typically expected. Please review and if applicable add a Con Med or comment for no medical treatment. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:23:33
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment is typically expected. Please review and if applicable add a Con Med or comment for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 06:54:58
User coded data point as SOC: Cardiac disorders, HLG: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 15:53:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 15:53:37
Data point term sent to Coder System	System	05 Sep 2020 15:52:48
User entered 'Congestive Heart failure'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:52:12

US3222117

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'un UNK 2015'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:52:12

US3222117

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '0'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:52:12

US3222117

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:52:12

US3222117

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:52:12

US3222117

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:52:12

US3222117

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered 'Jan 2015'	System	05 Sep 2020 15:52:12

US3222117

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered '2015'	System	05 Sep 2020 15:52:12

US3222117

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	05 Sep 2020 15:52:12

US3222117

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:02:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	05 Sep 2020 15:52:12

US3222117

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment is typically expected. Please review and if applicable add a Con Med or comment for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 19:42:16
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment is typically expected. Please review and if applicable add a Con Med or comment for no medical treatment. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:23:44
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment is typically expected. Please review and if applicable add a Con Med or comment for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 06:55:50
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 15:53:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 15:53:37
Data point term sent to Coder System	System	05 Sep 2020 15:52:47
User entered 'Hypertension'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:52:46

US3222117

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'un UNK 1991'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:52:46

US3222117

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '0'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:52:46

US3222117

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:52:46

US3222117

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:52:46

US3222117

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '0'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:52:46

US3222117

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered 'Jan 1991'	System	05 Sep 2020 15:52:46

US3222117

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered '1991'	System	05 Sep 2020 15:52:46

US3222117

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	05 Sep 2020 15:52:46

US3222117

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:02:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	05 Sep 2020 15:52:46

US3222117

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Sep 2020 15:54:37
Data point term sent to Coder	(b) (4)	
User entered 'Hypercholesterolemia'	Coder Import (b) (4)	05 Sep 2020 15:54:37
	(b) (4)	
	System	05 Sep 2020 15:53:48
	Amber Vasquez (b) (4)	05 Sep 2020 15:53:28
	(b) (4)	

US3222117

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'UN UNK 2000' reason for change: Data Entry Error	(b) (4) Diana Toney (b) (4)	26 Jan 2021 20:17:57
User entered 'un UNK 2005'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:53:28

US3222117

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:53:28

US3222117

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:53:28

US3222117

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:02:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:53:28

US3222117

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:02:02

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '0'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:53:28

US3222117

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered 'Jan 2000'	System	26 Jan 2021 20:17:57
User entered 'Jan 2005'	System	05 Sep 2020 15:53:28

US3222117

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered '2000'	System	26 Jan 2021 20:17:57
User entered '2005'	System	05 Sep 2020 15:53:28

US3222117

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:02:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	05 Sep 2020 15:53:28

US3222117

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:02:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	05 Sep 2020 15:53:28

US3222117

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:02:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGTT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 16:25:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 16:25:10
Data point term sent to Coder	System	07 Oct 2020 16:24:58
User entered 'COPD'	Albert Garcia (b) (4)	07 Oct 2020 16:24:14

US3222117

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:02:02

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'UN UNK 2002'	(b) (4) Albert Garcia (b) (4)	07 Oct 2020 16:24:14

US3222117

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:24:14

US3222117

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:24:14

US3222117

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:02:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) Albert Garcia (b) (4)	07 Oct 2020 16:24:14

US3222117

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:02:02

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:24:14

US3222117

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered 'Jan 2002'	System	07 Oct 2020 16:24:14

US3222117

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered '2002'	System	07 Oct 2020 16:24:14

US3222117

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:02:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	07 Oct 2020 16:24:14

US3222117

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:02:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	07 Oct 2020 16:24:14

US3222117

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Please verify the type of the DIABETIC NEUROPATHY - (HANDS AND FEET) (i.e. sensory or motor) and location (bilateral, left, right). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Nov 2020 08:35:20
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic peripheral neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 09:48:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 09:48:28
Data point term sent to Coder	System	02 Nov 2020 20:22:27
Query 'Per DM CLR: Please verify the type of the DIABETIC NEUROPATHY - (HANDS AND FEET) (i.e. sensory or motor) and location (bilateral, left, right). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	02 Nov 2020 20:22:07
Coding entries removed.	Albert Garcia (b) (4) (b) (4)	02 Nov 2020 20:21:46
User entered 'DIABETIC NEUROPATHY - (HANDS AND FEET) BILATERAL, SENSORY' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	02 Nov 2020 20:21:46
User opened query 'Per DM CLR: Please verify the type of the DIABETIC NEUROPATHY - (HANDS AND FEET) (i.e. sensory or motor) and location (bilateral, left, right). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 16:27:39

US3222117

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:02:02

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic peripheral neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 12:44:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 12:44:39
Data point term sent to Coder	System	20 Oct 2020 16:14:19
Coding entries removed.	(b) (4), (b) (6)	20 Oct 2020 16:13:22
User entered 'Diabetic NEUROPATHY - (Hands and feet)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 16:13:22
User coded data point as SOC: Nervous system disorders, HLT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:25:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:25:10
Data point term sent to Coder	System	07 Oct 2020 16:24:59
User entered 'NEUROPATHY'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:24:28

US3222117

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:02:02

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'UN UNK 2010'	(b) (4) Albert Garcia (b) (4)	07 Oct 2020 16:24:28

US3222117

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:24:28

US3222117

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:24:28

US3222117

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:02:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) Albert Garcia (b) (4)	07 Oct 2020 16:24:28

US3222117

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:24:28

US3222117

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered 'Jan 2010'	System	07 Oct 2020 16:24:28

US3222117

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered '2010'	System	07 Oct 2020 16:24:28

US3222117

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:02:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	07 Oct 2020 16:24:28

US3222117

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:02:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	07 Oct 2020 16:24:28

US3222117

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:02:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	(b) (4)	07 Oct 2020 16:25:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 16:25:10
Data point term sent to Coder	System	07 Oct 2020 16:24:59
User entered 'INSOMNIA'	Albert Garcia (b) (4)	07 Oct 2020 16:24:40
	(b) (4)	

US3222117

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:02:02

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'UN UNK 2015'	(b) (4) Albert Garcia (b) (4)	07 Oct 2020 16:24:40

US3222117

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:24:40

US3222117

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:24:40

US3222117

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:02:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) Albert Garcia (b) (4)	07 Oct 2020 16:24:40

US3222117

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:24:40

US3222117

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered 'Jan 2015'	System	07 Oct 2020 16:24:40

US3222117

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered '2015'	System	07 Oct 2020 16:24:40

US3222117

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:02:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	07 Oct 2020 16:24:40

US3222117

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:02:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	07 Oct 2020 16:24:40

US3222117

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Please specify the location (bilateral, left, right) of RESTLESS LEG SYNDROME. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Nov 2020 08:36:39
User coded data point as SOC: Nervous system disorders, HLG: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless legs syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 12:23:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 12:23:03
Data point term sent to Coder	System	02 Nov 2020 20:23:30
Query 'Per DM CLR: Please specify the location (bilateral, left, right) of RESTLESS LEG SYNDROME. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	02 Nov 2020 20:22:49
Coding entries removed.	Albert Garcia (b) (4) (b) (4)	02 Nov 2020 20:22:33
User entered 'RESTLESS LEG SYNDROME - BILATERAL' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	02 Nov 2020 20:22:33
User opened query 'Per DM CLR: Please specify the location (bilateral, left, right) of RESTLESS LEG SYNDROME. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 16:27:55
User coded data point as SOC: Nervous system disorders, HLG: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:25:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:25:10

US3222117

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:02:02

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	07 Oct 2020 16:24:59
User entered 'RESTLESS LEG SYNDROME'	Albert Garcia (b) (4)	07 Oct 2020 16:24:59
	(b) (4)	

US3222117

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:02:02

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'UN UNK 2005'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:24:59

US3222117

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:24:59

US3222117

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:24:59

US3222117

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:02:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) Albert Garcia (b) (4)	07 Oct 2020 16:24:59

US3222117

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:02:02

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:24:59

US3222117

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered 'Jan 2005'	System	07 Oct 2020 16:24:59

US3222117

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered '2005'	System	07 Oct 2020 16:24:59

US3222117

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:02:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	07 Oct 2020 16:24:59

US3222117

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:02:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	07 Oct 2020 16:24:59

US3222117

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:02:02

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Oct 2020 16:26:13
Data point term sent to Coder	(b) (4)	
User entered 'HYPERCHOLESTEROLEMIA'	Coder Import (b) (4)	07 Oct 2020 16:26:13
	(b) (4)	
	System	07 Oct 2020 16:26:00
	Albert Garcia (b) (4)	07 Oct 2020 16:25:14
	(b) (4)	

US3222117

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:02:02

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'UN UNK 2000'	(b) (4) Albert Garcia (b) (4)	07 Oct 2020 16:25:14

US3222117

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:25:14

US3222117

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:25:14

US3222117

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:02:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:25:14

US3222117

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:02:02

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:25:14

US3222117

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered 'Jan 2000'	System	07 Oct 2020 16:25:14

US3222117

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered '2000'	System	07 Oct 2020 16:25:14

US3222117

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:02:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	07 Oct 2020 16:25:14

US3222117

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:02:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	07 Oct 2020 16:25:14

US3222117

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:02:02

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Dec 2020 14:07:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Dec 2020 14:07:45
Data point term sent to Coder System	System	11 Dec 2020 14:07:28
User entered 'ALLERGIES - SEASONAL'	Albert Garcia (b) (4)	11 Dec 2020 14:06:48

US3222117

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:02:02

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'UN UNK 2002'	(b) (4) Albert Garcia (b) (4)	11 Dec 2020 14:06:48

US3222117

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '0'	(b) (4) Albert Garcia (b) (4)	11 Dec 2020 14:06:48

US3222117

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:02:02

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4)	11 Dec 2020 14:06:48

US3222117

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:02:02

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) Albert Garcia (b) (4)	11 Dec 2020 14:06:48

US3222117

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:02:02

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	11 Dec 2020 14:06:48

US3222117

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:02:02

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered 'Jan 2002'	System	11 Dec 2020 14:06:48

US3222117

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:02:02

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered '2002'	System	11 Dec 2020 14:06:48

US3222117

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:02:02

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	11 Dec 2020 14:06:48

US3222117

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:02:02

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	11 Dec 2020 14:06:48

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:54:50

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '12 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:54:50

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '15:55'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:54:50

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered '12 Aug 2020 15:55'	System	05 Sep 2020 15:54:50

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '172.7' cm	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:54:50
DataPoint set to visible.	(b) (4) System	12 Aug 2020 20:38:44

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '136.0' kg	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:54:50
DataPoint set to visible.	(b) (4) System	12 Aug 2020 20:38:44

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User closed query 'Per CDM: per sponsor review, BMI \geq 40 kg/m ² yet Severe obesity = No in Randomization Form. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 09:59:59
Query 'Per CDM: per sponsor review, BMI \geq 40 kg/m ² yet Severe obesity = No in Randomization Form. Please reconcile.' answered with 'data form updated' (Site from DM).	Jennifer Dittman (b) (4)	31 Mar 2021 21:58:07
User opened query 'Per CDM: per sponsor review, BMI \geq 40 kg/m ² yet Severe obesity = No in Randomization Form. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:22:22
User entered '45.59889'	System	05 Sep 2020 15:54:50
DataPoint set to visible.	System	12 Aug 2020 20:38:44

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered 'kg/m2'	System	05 Sep 2020 15:54:50
DataPoint set to visible.	System	12 Aug 2020 20:38:44

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:12:32
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 22:59:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 22:59:42
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 13:46:13
User entered '36.8' C	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:54:50

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty; reason for change Data Entry Error	(b) (4)	15 Sep 2020 22:59:42
User entered 'Oral (Oral)'	Albert Garcia (b) (4)	05 Sep 2020 15:54:50
	(b) (4)	

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:54:50

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 22:59:42
User entered '76'	Albert Garcia (b) (4)	15 Sep 2020 22:59:42
	(b) (4)	
	Amber Vasquez (b) (4)	05 Sep 2020 15:54:50
	(b) (4)	

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered 'bpm'	System	05 Sep 2020 15:54:50

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 22:59:42
User entered '16'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:54:50

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered 'breaths/min'	System	05 Sep 2020 15:54:50

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 22:59:42
User entered '142'	Albert Garcia (b) (4)	15 Sep 2020 22:59:42
	(b) (4)	
	Amber Vasquez (b) (4)	05 Sep 2020 15:54:50
	(b) (4)	

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered 'mmHg'	System	05 Sep 2020 15:54:50

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 22:59:42
User entered '64'	Albert Garcia (b) (4)	15 Sep 2020 22:59:42
	(b) (4)	
	Amber Vasquez (b) (4)	05 Sep 2020 15:54:50
	(b) (4)	

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered 'mmHg'	System	05 Sep 2020 15:54:50

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10

US3222117

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10

US3222117

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:55:07

US3222117

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	13 Sep 2020 15:09:53
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 15:25:23
User entered '12 Aug 2020'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:55:07

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	(b) (4) Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

[Emergency Response](#) (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

[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)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

[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)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

[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)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'RETIRED'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

[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)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

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)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '1'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:02:02

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:10

US3222117

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Jennifer Dittman (b) (4) (b) (4)	12 Aug 2020 20:39:19

US3222117

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '12 Aug 2020'	(b) (4) Jennifer Dittman (b) (4)	12 Aug 2020 20:39:19
	(b) (4)	

US3222117

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	12 Aug 2020 20:39:19

US3222117

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'VISIT1'	System	12 Aug 2020 20:39:19

US3222117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:54:37
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '12 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 20:44:14

US3222117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:54:37
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:00:47
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:00:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 20:44:14
User entered '186009' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 20:44:14

US3222117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:54:37
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 20:44:14

US3222117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

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)	30 Apr 2021 10:54:37
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'PER CDM: Please complete this section of the form. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 18:45:06
Query 'PER CDM: Please complete this section of the form. ' answered with 'data has been entered' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 17:41:49
User entered 'No (N)'	Amber Vasquez (b) (4) (b) (4)	02 Sep 2020 21:14:26
User opened query 'PER CDM: Please complete this section of the form. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 18:01:01
Query 'US3222117 ' canceled (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 18:00:45
User opened query 'US3222117 ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 18:00:43

US3222117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

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)	30 Apr 2021 10:54:37
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4) (b) (4)	02 Sep 2020 21:14:26

US3222117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:54:37
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Data hard locked.	(b) (4) (b) (4), (b) (6)	04 Apr 2021 18:06:25
Signature has been broken.	Jennifer Dittman (b) (4)	31 Mar 2021 21:57:49
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Jennifer Dittman (b) (4)	31 Mar 2021 21:57:49
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	02 Sep 2020 21:14:26

US3222117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:54:37
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	02 Sep 2020 21:14:26
	(b) (4)	

US3222117

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:02:02

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:54:37
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 08:53:37
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	02 Sep 2020 21:14:26
	(b) (4)	

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:44:39
Query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:21:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:21:29
User opened query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:22:21
User entered empty.	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:44:36
Query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:21:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:21:29
User opened query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:22:24
User entered empty.	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:44:39
Query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:21:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:21:29
User opened query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:22:21
User entered empty.	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:44:36
Query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:21:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:21:29
User opened query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:22:24
User entered empty.	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '12 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '16:00'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '12 Aug 2020 16:00'	System	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '36.8' C	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Oral (Oral)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '75'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'bpm'	System	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '16'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'breaths/min'	System	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '141'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'mmHg'	System	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '62'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'mmHg'	System	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:44:39
Query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:21:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:21:29
User opened query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:22:21
User entered empty.	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:02:02

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 10:44:36
Query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:21:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 14:21:29
User opened query ' Per CDM: per CCGs pages 15-16, ND should be recorded HEIGHT and WEIGHT. Please enter "ND" into field' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 13:22:24
User entered empty.	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '12 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '17:20'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '12 Aug 2020 17:20'	System	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '36.9' C	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Oral (Oral)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '69'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'bpm'	System	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '16'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'breaths/min'	System	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '139'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'mmHg'	System	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '70'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'mmHg'	System	05 Sep 2020 15:56:58

US3222117

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:57:12

US3222117

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '12 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:57:12

US3222117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:39

US3222117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:39

US3222117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

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)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Jennifer Dittman (b) (4)	12 Aug 2020 20:53:39

US3222117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 20:53:39

US3222117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '12 Aug 2020'	(b) (4) Jennifer Dittman (b) (4)	12 Aug 2020 20:53:39
	(b) (4)	

US3222117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '16:49'	(b) (4) Jennifer Dittman (b) (4)	12 Aug 2020 20:53:39
	(b) (4)	

US3222117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '12 Aug 2020 16:49'	System	12 Aug 2020 20:53:39

US3222117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Left Arm (LEFT ARM)'	(b) (4) Jennifer Dittman (b) (4)	12 Aug 2020 20:53:39

US3222117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'ONCE'	System	12 Aug 2020 20:53:39

US3222117

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 20:53:39

US3222117

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:57:30

US3222117

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '12 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:57:30

US3222117

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '16:40'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:57:30

US3222117

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '12 Aug 2020 16:40'	System	05 Sep 2020 15:57:30

US3222117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:02:02

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '12 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:57:47

US3222117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:57:47

US3222117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:57:47

US3222117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '16:42'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:57:47

US3222117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '12 Aug 2020 16:42'	System	05 Sep 2020 15:57:47

US3222117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:57:47

US3222117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:57:47

US3222117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:57:47

US3222117

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered empty.	System	05 Sep 2020 15:57:47

US3222117

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:57:53

US3222117

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '1'	System	05 Sep 2020 15:57:53

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-12T17:25:02', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '59395d1f-6dec-40f6-b6d6-13dacf9f87bf' User entered 'Yes (Y)'	System	12 Aug 2020 21:25:42
	System	12 Aug 2020 21:25:42

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-12T17:25:14', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '59395d1f-6dec-40f6-b6d6-13dacf9f87bf' User entered '98.4'	System	12 Aug 2020 21:25:42
	System	12 Aug 2020 21:25:42

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-12T17:25:20', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '59395d1f-6dec-40f6-b6d6-13dacf9f87bf'	System	12 Aug 2020 21:25:42
User entered 'No (N)'	System	12 Aug 2020 21:25:42

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-12T17:25:29', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '59395d1f-6dec-40f6-b6d6-13dacf9f87bf' User entered '12 Aug 2020 17:25'	System	12 Aug 2020 21:25:42
	System	12 Aug 2020 21:25:42

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '12 Aug 2020 17:09'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '12 Aug 2020 19:39'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-13T06:44:08', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'b176d5a1-94af-44a9-b8fa-790a0fa61030'	System	13 Aug 2020 10:44:33
User entered 'Yes (Y)'	System	13 Aug 2020 10:44:33

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-13T06:44:17', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'b176d5a1-94af-44a9-b8fa-790a0fa61030'	System	13 Aug 2020 10:44:33
User entered '95.8'	System	13 Aug 2020 10:44:33

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-13T06:44:22', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'b176d5a1-94af-44a9-b8fa-790a0fa61030'	System	13 Aug 2020 10:44:33
User entered 'No (N)'	System	13 Aug 2020 10:44:33

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-13T06:44:28', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'b176d5a1-94af-44a9-b8fa-790a0fa61030'	System	13 Aug 2020 10:44:33
User entered '13 Aug 2020 06:44'	System	13 Aug 2020 10:44:33

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '12 Aug 2020 20:34'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 2'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 3'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-14T12:03:55', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '97bf256f-eb31-4763-87f4-761762e009d3'	System	14 Aug 2020 16:04:25
User entered 'Yes (Y)'	System	14 Aug 2020 16:04:25

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-14T12:04:05', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '97bf256f-eb31-4763-87f4-761762e009d3'	System	14 Aug 2020 16:04:25
User entered '97.9'	System	14 Aug 2020 16:04:25

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-14T12:04:10', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '97bf256f-eb31-4763-87f4-761762e009d3'	System	14 Aug 2020 16:04:25
User entered 'No (N)'	System	14 Aug 2020 16:04:25

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-14T12:04:17', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '97bf256f-eb31-4763-87f4-761762e009d3'	System	14 Aug 2020 16:04:25
User entered '14 Aug 2020 12:04'	System	14 Aug 2020 16:04:25

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 4'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-15T14:30:28', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'f775857e-3f76-4cb8-90f6-6298ac908e25'	System	15 Aug 2020 18:30:52
User entered 'Yes (Y)'	System	15 Aug 2020 18:30:52

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-15T14:30:37', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'f775857e-3f76-4cb8-90f6-6298ac908e25'	System	15 Aug 2020 18:30:52
User entered '97.7'	System	15 Aug 2020 18:30:52

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-15T14:30:42', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'f775857e-3f76-4cb8-90f6-6298ac908e25'	System	15 Aug 2020 18:30:52
User entered 'No (N)'	System	15 Aug 2020 18:30:52

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-15T14:30:48', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'f775857e-3f76-4cb8-90f6-6298ac908e25'	System	15 Aug 2020 18:30:52
User entered '15 Aug 2020 14:30'	System	15 Aug 2020 18:30:52

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 5'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 6'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 7'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-18T20:17:43', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '302fa23a-e8c8-4c69-922f-3d06627c8cd6'	System	19 Aug 2020 00:18:09
User entered 'Yes (Y)'	System	19 Aug 2020 00:18:09

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-18T20:17:52', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '302fa23a-e8c8-4c69-922f-3d06627c8cd6'	System	19 Aug 2020 00:18:09
User entered '98.2'	System	19 Aug 2020 00:18:09

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-18T20:17:56', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '302fa23a-e8c8-4c69-922f-3d06627c8cd6'	System	19 Aug 2020 00:18:09
User entered 'No (N)'	System	19 Aug 2020 00:18:09

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-18T20:18:03', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '302fa23a-e8c8-4c69-922f-3d06627c8cd6'	System	19 Aug 2020 00:18:09
User entered '18 Aug 2020 20:18'	System	19 Aug 2020 00:18:09

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-12T17:25:56', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2c01532c-01ef-49b1-91d5-033e307b9d21'	System	12 Aug 2020 21:26:32
User entered 'None (1)'	System	12 Aug 2020 21:26:32

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-12T17:26:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2c01532c-01ef-49b1-91d5-033e307b9d21'	System	12 Aug 2020 21:26:32
User entered 'No (N)'	System	12 Aug 2020 21:26:32

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-12T17:26:11', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2c01532c-01ef-49b1-91d5-033e307b9d21'	System	12 Aug 2020 21:26:32
User entered 'No (N)'	System	12 Aug 2020 21:26:32

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-12T17:26:16', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2c01532c-01ef-49b1-91d5-033e307b9d21'	System	12 Aug 2020 21:26:32
User entered 'None (1)'	System	12 Aug 2020 21:26:32

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-12T17:26:22', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2c01532c-01ef-49b1-91d5-033e307b9d21'	System	12 Aug 2020 21:26:32
User entered '12 Aug 2020 17:26'	System	12 Aug 2020 21:26:32

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '12 Aug 2020 17:09'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '12 Aug 2020 19:39'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-13T06:45:24', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'deed09d2-a199-4d30-8357-fe15331cabaf'	System	13 Aug 2020 10:45:39
User entered 'None (1)'	System	13 Aug 2020 10:45:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-13T06:44:49', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'deed09d2-a199-4d30-8357-fe15331cabaf'	System	13 Aug 2020 10:45:39
User entered 'No (N)'	System	13 Aug 2020 10:45:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-13T06:45:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'deed09d2-a199-4d30-8357-fe15331cabaf'	System	13 Aug 2020 10:45:39
User entered 'No (N)'	System	13 Aug 2020 10:45:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-13T06:45:06', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'deed09d2-a199-4d30-8357-fe15331cabaf'	System	13 Aug 2020 10:45:39
User entered 'None (1)'	System	13 Aug 2020 10:45:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-13T06:45:35', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'deed09d2-a199-4d30-8357-fe15331cabaf'	System	13 Aug 2020 10:45:39
User entered '13 Aug 2020 06:45'	System	13 Aug 2020 10:45:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '12 Aug 2020 20:34'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 2'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 3'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-14T12:04:32', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '80edcc3e-92ef-470d-97fd-3f9856a8cb98'	System	14 Aug 2020 16:05:01
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 16:05:01

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-14T12:04:35', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '80edcc3e-92ef-470d-97fd-3f9856a8cb98'	System	14 Aug 2020 16:05:01
User entered 'No (N)'	System	14 Aug 2020 16:05:01

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-14T12:04:51', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '80edcc3e-92ef-470d-97fd-3f9856a8cb98'	System	14 Aug 2020 16:05:01
User entered 'No (N)'	System	14 Aug 2020 16:05:01

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-14T12:04:44', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '80edcc3e-92ef-470d-97fd-3f9856a8cb98'	System	14 Aug 2020 16:05:01
User entered 'None (1)'	System	14 Aug 2020 16:05:01

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-14T12:04:54', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '80edcc3e-92ef-470d-97fd-3f9856a8cb98'	System	14 Aug 2020 16:05:01
User entered '14 Aug 2020 12:04'	System	14 Aug 2020 16:05:01

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 4'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-15T14:31:02', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'bb3fe01a-5923-4df8-9bf5-d495b5367de1'	System	15 Aug 2020 18:31:21
User entered 'None (1)'	System	15 Aug 2020 18:31:21

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-15T14:31:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'bb3fe01a-5923-4df8-9bf5-d495b5367de1'	System	15 Aug 2020 18:31:21
User entered 'No (N)'	System	15 Aug 2020 18:31:21

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-15T14:31:07', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'bb3fe01a-5923-4df8-9bf5-d495b5367de1'	System	15 Aug 2020 18:31:21
User entered 'No (N)'	System	15 Aug 2020 18:31:21

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-15T14:31:11', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'bb3fe01a-5923-4df8-9bf5-d495b5367de1'	System	15 Aug 2020 18:31:21
User entered 'None (1)'	System	15 Aug 2020 18:31:21

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-15T14:31:17', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'bb3fe01a-5923-4df8-9bf5-d495b5367de1'	System	15 Aug 2020 18:31:21
User entered '15 Aug 2020 14:31'	System	15 Aug 2020 18:31:21

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 5'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 6'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 7'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-18T20:18:09', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ae7d99f8-522f-482e-a690-b772c3b4a4ac'	System	19 Aug 2020 00:18:31
User entered 'None (1)'	System	19 Aug 2020 00:18:31

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-18T20:18:14', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ae7d99f8-522f-482e-a690-b772c3b4a4ac'	System	19 Aug 2020 00:18:31
User entered 'No (N)'	System	19 Aug 2020 00:18:31

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-18T20:18:18', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ae7d99f8-522f-482e-a690-b772c3b4a4ac'	System	19 Aug 2020 00:18:31
User entered 'No (N)'	System	19 Aug 2020 00:18:31

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-18T20:18:22', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ae7d99f8-522f-482e-a690-b772c3b4a4ac'	System	19 Aug 2020 00:18:31
User entered 'None (1)'	System	19 Aug 2020 00:18:31

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-18T20:18:27', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ae7d99f8-522f-482e-a690-b772c3b4a4ac'	System	19 Aug 2020 00:18:31
User entered '18 Aug 2020 20:18'	System	19 Aug 2020 00:18:31

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-12T17:26:30', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2ff0e112-825c-4a1c-a67f-869eef11e292'	System	12 Aug 2020 21:27:11
User entered 'None (0)'	System	12 Aug 2020 21:27:11

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-12T17:26:34', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2ff0e112-825c-4a1c-a67f-869eef11e292'	System	12 Aug 2020 21:27:11
User entered 'None (0)'	System	12 Aug 2020 21:27:11

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-12T17:26:38', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2ff0e112-825c-4a1c-a67f-869eef11e292'	System	12 Aug 2020 21:27:11
User entered 'None (0)'	System	12 Aug 2020 21:27:11

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-12T17:26:44', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2ff0e112-825c-4a1c-a67f-869eef11e292'	System	12 Aug 2020 21:27:11
User entered 'None (0)'	System	12 Aug 2020 21:27:11

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-12T17:26:47', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2ff0e112-825c-4a1c-a67f-869eef11e292'	System	12 Aug 2020 21:27:11
User entered 'None (0)'	System	12 Aug 2020 21:27:11

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-12T17:26:50', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2ff0e112-825c-4a1c-a67f-869eef11e292'	System	12 Aug 2020 21:27:11
User entered 'None (0)'	System	12 Aug 2020 21:27:11

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-12T17:27:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2ff0e112-825c-4a1c-a67f-869eef11e292'	System	12 Aug 2020 21:27:11
User entered 'No (N)'	System	12 Aug 2020 21:27:11

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-12T17:27:05', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2ff0e112-825c-4a1c-a67f-869eef11e292'	System	12 Aug 2020 21:27:11
User entered '12 Aug 2020 17:27'	System	12 Aug 2020 21:27:11

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '12 Aug 2020 17:09'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '12 Aug 2020 19:39'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-13T06:45:47', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '072ffcba-74e5-4d46-b330-1617aad6baee'	System	13 Aug 2020 10:46:27
User entered 'None (0)'	System	13 Aug 2020 10:46:27

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-13T06:45:51', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '072ffcba-74e5-4d46-b330-1617aad6baee'	System	13 Aug 2020 10:46:27
User entered 'None (0)'	System	13 Aug 2020 10:46:27

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-13T06:45:58', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '072ffcba-74e5-4d46-b330-1617aad6baee'	System	13 Aug 2020 10:46:27
User entered 'None (0)'	System	13 Aug 2020 10:46:27

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-13T06:46:03', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '072ffcba-74e5-4d46-b330-1617aad6baee'	System	13 Aug 2020 10:46:27
User entered 'None (0)'	System	13 Aug 2020 10:46:27

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-13T06:46:09', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '072ffcba-74e5-4d46-b330-1617aad6baee'	System	13 Aug 2020 10:46:27
User entered 'None (0)'	System	13 Aug 2020 10:46:27

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-13T06:46:12', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '072ffcba-74e5-4d46-b330-1617aad6baee'	System	13 Aug 2020 10:46:27
User entered 'None (0)'	System	13 Aug 2020 10:46:27

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-13T06:46:17', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '072ffcba-74e5-4d46-b330-1617aad6baee'	System	13 Aug 2020 10:46:27
User entered 'No (N)'	System	13 Aug 2020 10:46:27

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-13T06:46:24', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '072ffcba-74e5-4d46-b330-1617aad6baee'	System	13 Aug 2020 10:46:27
User entered '13 Aug 2020 06:46'	System	13 Aug 2020 10:46:27

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '12 Aug 2020 20:34'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 2'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 3'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-14T12:04:59', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '1af2be9a-0b44-4aa2-b1f4-f5a6e581dc82'	System	14 Aug 2020 16:05:39
User entered 'None (0)'	System	14 Aug 2020 16:05:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-14T12:05:07', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '1af2be9a-0b44-4aa2-b1f4-f5a6e581dc82'	System	14 Aug 2020 16:05:39
User entered 'Some interference with activity (2)'	System	14 Aug 2020 16:05:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-14T12:05:13', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '1af2be9a-0b44-4aa2-b1f4-f5a6e581dc82'	System	14 Aug 2020 16:05:39
User entered 'No interference with activity (1)'	System	14 Aug 2020 16:05:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-14T12:05:18', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '1af2be9a-0b44-4aa2-b1f4-f5a6e581dc82'	System	14 Aug 2020 16:05:39
User entered 'None (0)'	System	14 Aug 2020 16:05:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-14T12:05:21', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '1af2be9a-0b44-4aa2-b1f4-f5a6e581dc82'	System	14 Aug 2020 16:05:39
User entered 'None (0)'	System	14 Aug 2020 16:05:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-14T12:05:24', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '1af2be9a-0b44-4aa2-b1f4-f5a6e581dc82'	System	14 Aug 2020 16:05:39
User entered 'None (0)'	System	14 Aug 2020 16:05:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-14T12:05:28', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '1af2be9a-0b44-4aa2-b1f4-f5a6e581dc82'	System	14 Aug 2020 16:05:39
User entered 'No (N)'	System	14 Aug 2020 16:05:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-14T12:05:33', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '1af2be9a-0b44-4aa2-b1f4-f5a6e581dc82'	System	14 Aug 2020 16:05:39
User entered '14 Aug 2020 12:05'	System	14 Aug 2020 16:05:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 4'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-15T14:31:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ff3c63ca-83db-41c0-8285-50a3a92ee03f' User entered 'None (0)'	System	15 Aug 2020 18:32:01
	System	15 Aug 2020 18:32:01

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-15T14:31:32', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ff3c63ca-83db-41c0-8285-50a3a92ee03f' User entered 'None (0)'	System	15 Aug 2020 18:32:01
	System	15 Aug 2020 18:32:01

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-15T14:31:35', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ff3c63ca-83db-41c0-8285-50a3a92ee03f' User entered 'None (0)'	System	15 Aug 2020 18:32:01
	System	15 Aug 2020 18:32:01

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-15T14:31:38', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ff3c63ca-83db-41c0-8285-50a3a92ee03f' User entered 'None (0)'	System	15 Aug 2020 18:32:01
	System	15 Aug 2020 18:32:01

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-15T14:31:40', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ff3c63ca-83db-41c0-8285-50a3a92ee03f' User entered 'None (0)'	System	15 Aug 2020 18:32:01
	System	15 Aug 2020 18:32:01

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-15T14:31:44', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ff3c63ca-83db-41c0-8285-50a3a92ee03f' User entered 'None (0)'	System	15 Aug 2020 18:32:01
	System	15 Aug 2020 18:32:01

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-15T14:31:51', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ff3c63ca-83db-41c0-8285-50a3a92ee03f' User entered 'No (N)'	System	15 Aug 2020 18:32:01
	System	15 Aug 2020 18:32:01

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-15T14:31:58', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ff3c63ca-83db-41c0-8285-50a3a92ee03f'	System	15 Aug 2020 18:32:01
User entered '15 Aug 2020 14:31'	System	15 Aug 2020 18:32:01

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 5'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 6'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 7'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-18T20:18:32', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '081b5086-1441-4c3d-b98f-c6f55a7b1b68'	System	19 Aug 2020 00:19:05
User entered 'None (0)'	System	19 Aug 2020 00:19:05

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-18T20:18:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '081b5086-1441-4c3d-b98f-c6f55a7b1b68'	System	19 Aug 2020 00:19:05
User entered 'None (0)'	System	19 Aug 2020 00:19:05

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-18T20:18:41', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '081b5086-1441-4c3d-b98f-c6f55a7b1b68'	System	19 Aug 2020 00:19:05
User entered 'None (0)'	System	19 Aug 2020 00:19:05

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-18T20:18:45', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '081b5086-1441-4c3d-b98f-c6f55a7b1b68'	System	19 Aug 2020 00:19:05
User entered 'None (0)'	System	19 Aug 2020 00:19:05

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-18T20:18:47', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '081b5086-1441-4c3d-b98f-c6f55a7b1b68'	System	19 Aug 2020 00:19:05
User entered 'None (0)'	System	19 Aug 2020 00:19:05

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-18T20:18:50', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '081b5086-1441-4c3d-b98f-c6f55a7b1b68'	System	19 Aug 2020 00:19:05
User entered 'None (0)'	System	19 Aug 2020 00:19:05

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-18T20:18:54', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '081b5086-1441-4c3d-b98f-c6f55a7b1b68'	System	19 Aug 2020 00:19:05
User entered 'No (N)'	System	19 Aug 2020 00:19:05

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-08-18T20:18:59', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '081b5086-1441-4c3d-b98f-c6f55a7b1b68'	System	19 Aug 2020 00:19:05
User entered '18 Aug 2020 20:18'	System	19 Aug 2020 00:19:05

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 20:53:39

US3222117

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:58:29

US3222117

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '19 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:58:29

US3222117

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Contact Made (CONTACT MADE)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:58:29

US3222117

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:58:29

US3222117

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:58:33

US3222117

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '1'	System	05 Sep 2020 15:58:33

US3222117

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:58:52

US3222117

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '26 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:58:52

US3222117

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Contact Made (CONTACT MADE)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:58:52

US3222117

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:58:52

US3222117

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:58:57

US3222117

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '1'	System	05 Sep 2020 15:58:57

US3222117

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:59:24

US3222117

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '2 Sep 2020'	(b) (4) Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:59:24

US3222117

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Contact Made (CONTACT MADE)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:59:24

US3222117

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 15:59:24

US3222117

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 15:59:29

US3222117

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '1'	System	05 Sep 2020 15:59:29

US3222117

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	(b) (4) Thais Truffa (b) (4)	10 Sep 2020 15:25:23

US3222117

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '10 Sep 2020'	(b) (4) Thais Truffa (b) (4)	10 Sep 2020 15:25:23

US3222117

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Home (Home)'	(b) (4) Thais Truffa (b) (4)	10 Sep 2020 15:25:23

US3222117

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'VISIT2'	System	10 Sep 2020 15:25:23

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User accepted default value 'Pre-Dose (PREDOSE)'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '10 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '10:19'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '10 Sep 2020 10:19'	System	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '36.2' C	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Oral (Oral)'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '64'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'bpm'	System	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '16'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'breaths/min'	System	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '130'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'mmHg'	System	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '70'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'mmHg'	System	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User accepted default value 'Post-Dose (POSTDOSE)'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4) System	10 Sep 2020 15:59:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Albert Garcia (b) (4)	10 Sep 2020 15:59:03
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4) System	10 Sep 2020 15:58:46
User entered 'No (N)'	Albert Garcia (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '10 Sep 2020'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '11:49'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '10 Sep 2020 11:49'	System	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '36.5' C	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Oral (Oral)'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '64'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'bpm'	System	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '16'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'breaths/min'	System	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '138'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'mmHg'	System	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '68'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'mmHg'	System	10 Sep 2020 15:58:46

US3222117

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:59:17

US3222117

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '10 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:59:17

US3222117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	(b) (4) Thais Truffa (b) (4)	10 Sep 2020 15:27:57

US3222117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) Thais Truffa (b) (4)	10 Sep 2020 15:27:57

US3222117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

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)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) Thais Truffa (b) (4)	10 Sep 2020 15:27:57

US3222117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 15:27:57

US3222117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '10 Sep 2020'	(b) (4) Thais Truffa (b) (4)	10 Sep 2020 15:27:57

US3222117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '11:16'	(b) (4) Thais Truffa (b) (4)	10 Sep 2020 15:27:57

US3222117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '10 Sep 2020 11:16'	System	10 Sep 2020 15:27:57

US3222117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Left Arm (LEFT ARM)'	(b) (4) Thais Truffa (b) (4)	10 Sep 2020 15:27:57

US3222117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'ONCE'	System	10 Sep 2020 15:27:57

US3222117

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:02:02

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 15:27:57

US3222117

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:59:35

US3222117

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '10 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:59:35

US3222117

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '10:32'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:59:35

US3222117

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '10 Sep 2020 10:32'	System	10 Sep 2020 15:59:35

US3222117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:02:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '10 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:59:52

US3222117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:59:52

US3222117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:59:52

US3222117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '10:35'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:59:52

US3222117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:02:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '10 Sep 2020 10:35'	System	10 Sep 2020 15:59:52

US3222117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:59:52

US3222117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:59:52

US3222117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 15:59:52

US3222117

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:02:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered empty.	System	10 Sep 2020 15:59:52

US3222117

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	10 Sep 2020 16:00:18

US3222117

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '1'	System	10 Sep 2020 16:00:18

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-10T13:51:15', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6b7b348d-e7bb-4f99-bfa3-e986f5ba1bff'	System	10 Sep 2020 17:51:42
User entered 'Yes (Y)'	System	10 Sep 2020 17:51:42

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-10T13:51:24', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6b7b348d-e7bb-4f99-bfa3-e986f5ba1bff'	System	10 Sep 2020 17:51:42
User entered '97.8'	System	10 Sep 2020 17:51:42

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-10T13:51:30', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6b7b348d-e7bb-4f99-bfa3-e986f5ba1bff'	System	10 Sep 2020 17:51:42
User entered 'No (N)'	System	10 Sep 2020 17:51:42

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-10T13:51:35', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6b7b348d-e7bb-4f99-bfa3-e986f5ba1bff' User entered '10 Sep 2020 13:51'	System	10 Sep 2020 17:51:42
	System	10 Sep 2020 17:51:42

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '10 Sep 2020 11:36'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '10 Sep 2020 14:06'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '10 Sep 2020 15:01'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 2'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-11T21:26:28', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '8eb732e0-a154-402d-b277-7b417a5cfc62'	System	12 Sep 2020 01:26:51
User entered 'Yes (Y)'	System	12 Sep 2020 01:26:51

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-11T21:26:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '8eb732e0-a154-402d-b277-7b417a5cfc62'	System	12 Sep 2020 01:26:51
User entered '97.6'	System	12 Sep 2020 01:26:51

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-11T21:26:41', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '8eb732e0-a154-402d-b277-7b417a5cfc62'	System	12 Sep 2020 01:26:51
User entered 'No (N)'	System	12 Sep 2020 01:26:51

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-11T21:26:46', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '8eb732e0-a154-402d-b277-7b417a5cfc62'	System	12 Sep 2020 01:26:51
User entered '11 Sep 2020 21:26'	System	12 Sep 2020 01:26:51

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 3'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-12T18:15:27', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '7c534ee0-915e-46bf-b1d2-ab85f258ba14'	System	12 Sep 2020 22:16:09
User entered 'Yes (Y)'	System	12 Sep 2020 22:16:09

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-12T18:15:34', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '7c534ee0-915e-46bf-b1d2-ab85f258ba14'	System	12 Sep 2020 22:16:09
User entered '97.8'	System	12 Sep 2020 22:16:09

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-12T18:15:38', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '7c534ee0-915e-46bf-b1d2-ab85f258ba14'	System	12 Sep 2020 22:16:09
User entered 'No (N)'	System	12 Sep 2020 22:16:09

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-12T18:15:46', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '7c534ee0-915e-46bf-b1d2-ab85f258ba14'	System	12 Sep 2020 22:16:09
User entered '12 Sep 2020 18:15'	System	12 Sep 2020 22:16:09

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 4'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 5'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 6'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-15T13:22:14', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '8af3eed7-d267-46ca-86ef-254486ed4418'	System	15 Sep 2020 17:22:40
User entered 'Yes (Y)'	System	15 Sep 2020 17:22:40

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-15T13:22:23', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '8af3eed7-d267-46ca-86ef-254486ed4418'	System	15 Sep 2020 17:22:40
User entered '97.2'	System	15 Sep 2020 17:22:40

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-15T13:22:32', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '8af3eed7-d267-46ca-86ef-254486ed4418'	System	15 Sep 2020 17:22:40
User entered 'No (N)'	System	15 Sep 2020 17:22:40

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-15T13:22:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '8af3eed7-d267-46ca-86ef-254486ed4418'	System	15 Sep 2020 17:22:40
User entered '15 Sep 2020 13:22'	System	15 Sep 2020 17:22:40

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 7'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-10T13:51:45', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'a4c0cc10-50dc-4048-bbaf-8a6a8d50bf88'	System	10 Sep 2020 17:52:12
User entered 'None (1)'	System	10 Sep 2020 17:52:12

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-10T13:51:50', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'a4c0cc10-50dc-4048-bbaf-8a6a8d50bf88'	System	10 Sep 2020 17:52:12
User entered 'No (N)'	System	10 Sep 2020 17:52:12

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-10T13:51:55', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'a4c0cc10-50dc-4048-bbaf-8a6a8d50bf88'	System	10 Sep 2020 17:52:12
User entered 'No (N)'	System	10 Sep 2020 17:52:12

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-10T13:52:01', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'a4c0cc10-50dc-4048-bbaf-8a6a8d50bf88'	System	10 Sep 2020 17:52:12
User entered 'None (1)'	System	10 Sep 2020 17:52:12

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-10T13:52:05', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'a4c0cc10-50dc-4048-bbaf-8a6a8d50bf88'	System	10 Sep 2020 17:52:12
User entered '10 Sep 2020 13:52'	System	10 Sep 2020 17:52:12

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '10 Sep 2020 11:36'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '10 Sep 2020 14:06'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '10 Sep 2020 15:01'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 2'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-11T21:27:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'd8fbc337-163a-4235-a298-8cc606cc3733'	System	12 Sep 2020 01:27:20
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 01:27:20

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-11T21:27:03', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'd8fbc337-163a-4235-a298-8cc606cc3733'	System	12 Sep 2020 01:27:20
User entered 'No (N)'	System	12 Sep 2020 01:27:20

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-11T21:27:08', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'd8fbc337-163a-4235-a298-8cc606cc3733'	System	12 Sep 2020 01:27:20
User entered 'No (N)'	System	12 Sep 2020 01:27:20

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-11T21:27:12', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'd8fbc337-163a-4235-a298-8cc606cc3733'	System	12 Sep 2020 01:27:20
User entered 'None (1)'	System	12 Sep 2020 01:27:20

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-11T21:27:17', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'd8fbc337-163a-4235-a298-8cc606cc3733'	System	12 Sep 2020 01:27:20
User entered '11 Sep 2020 21:27'	System	12 Sep 2020 01:27:20

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 3'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-12T18:15:59', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '8f6b30b2-a8c7-46bf-b358-412df5c81216'	System	12 Sep 2020 22:16:23
User entered 'None (1)'	System	12 Sep 2020 22:16:23

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-12T18:16:02', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '8f6b30b2-a8c7-46bf-b358-412df5c81216'	System	12 Sep 2020 22:16:23
User entered 'No (N)'	System	12 Sep 2020 22:16:23

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-12T18:16:06', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '8f6b30b2-a8c7-46bf-b358-412df5c81216'	System	12 Sep 2020 22:16:23
User entered 'No (N)'	System	12 Sep 2020 22:16:23

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-12T18:16:10', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '8f6b30b2-a8c7-46bf-b358-412df5c81216'	System	12 Sep 2020 22:16:23
User entered 'None (1)'	System	12 Sep 2020 22:16:23

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-12T18:16:14', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '8f6b30b2-a8c7-46bf-b358-412df5c81216'	System	12 Sep 2020 22:16:23
User entered '12 Sep 2020 18:16'	System	12 Sep 2020 22:16:23

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 4'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 5'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 6'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-15T13:22:42', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'f29b9717-13a2-4558-ba3c-98b6bff8fd80'	System	15 Sep 2020 17:23:04
User entered 'None (1)'	System	15 Sep 2020 17:23:04

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-15T13:22:47', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'f29b9717-13a2-4558-ba3c-98b6bf8fd80'	System	15 Sep 2020 17:23:04
User entered 'No (N)'	System	15 Sep 2020 17:23:04

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-15T13:22:50', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'f29b9717-13a2-4558-ba3c-98b6bff8fd80'	System	15 Sep 2020 17:23:04
User entered 'No (N)'	System	15 Sep 2020 17:23:04

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-15T13:22:53', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'f29b9717-13a2-4558-ba3c-98b6bff8fd80'	System	15 Sep 2020 17:23:04
User entered 'None (1)'	System	15 Sep 2020 17:23:04

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-15T13:22:57', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'f29b9717-13a2-4558-ba3c-98b6bff8fd80'	System	15 Sep 2020 17:23:04
User entered '15 Sep 2020 13:22'	System	15 Sep 2020 17:23:04

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 7'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-10T13:52:11', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '638cf6bd-deec-448d-9f6a-36991adec4f0'	System	10 Sep 2020 17:52:37
User entered 'None (0)'	System	10 Sep 2020 17:52:37

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-10T13:52:14', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '638cf6bd-deec-448d-9f6a-36991adec4f0'	System	10 Sep 2020 17:52:37
User entered 'None (0)'	System	10 Sep 2020 17:52:37

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-10T13:52:17', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '638cf6bd-deec-448d-9f6a-36991adec4f0'	System	10 Sep 2020 17:52:37
User entered 'None (0)'	System	10 Sep 2020 17:52:37

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-10T13:52:20', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '638cf6bd-deec-448d-9f6a-36991adec4f0'	System	10 Sep 2020 17:52:37
User entered 'None (0)'	System	10 Sep 2020 17:52:37

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-10T13:52:22', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '638cf6bd-deec-448d-9f6a-36991adec4f0'	System	10 Sep 2020 17:52:37
User entered 'None (0)'	System	10 Sep 2020 17:52:37

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-10T13:52:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '638cf6bd-deec-448d-9f6a-36991adec4f0'	System	10 Sep 2020 17:52:37
User entered 'None (0)'	System	10 Sep 2020 17:52:37

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-10T13:52:28', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '638cf6bd-deec-448d-9f6a-36991adec4f0' User entered 'No (N)'	System	10 Sep 2020 17:52:37
	System	10 Sep 2020 17:52:37

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-10T13:52:32', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '638cf6bd-deec-448d-9f6a-36991adec4f0' User entered '10 Sep 2020 13:52'	System	10 Sep 2020 17:52:37
	System	10 Sep 2020 17:52:37

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '10 Sep 2020 11:36'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '10 Sep 2020 14:06'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '10 Sep 2020 15:01'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 2'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-11T21:27:24', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '327176bb-4fc4-4b4e-ae4c-71fa7e3b9771'	System	12 Sep 2020 01:27:56
User entered 'None (0)'	System	12 Sep 2020 01:27:56

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-11T21:27:28', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '327176bb-4fc4-4b4e-ae4c-71fa7e3b9771'	System	12 Sep 2020 01:27:56
User entered 'None (0)'	System	12 Sep 2020 01:27:56

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-11T21:27:32', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '327176bb-4fc4-4b4e-ae4c-71fa7e3b9771'	System	12 Sep 2020 01:27:56
User entered 'None (0)'	System	12 Sep 2020 01:27:56

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-11T21:27:34', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '327176bb-4fc4-4b4e-ae4c-71fa7e3b9771'	System	12 Sep 2020 01:27:56
User entered 'None (0)'	System	12 Sep 2020 01:27:56

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-11T21:27:38', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '327176bb-4fc4-4b4e-ae4c-71fa7e3b9771'	System	12 Sep 2020 01:27:56
User entered 'None (0)'	System	12 Sep 2020 01:27:56

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-11T21:27:43', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '327176bb-4fc4-4b4e-ae4c-71fa7e3b9771'	System	12 Sep 2020 01:27:56
User entered 'None (0)'	System	12 Sep 2020 01:27:56

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-11T21:27:47', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '327176bb-4fc4-4b4e-ae4c-71fa7e3b9771'	System	12 Sep 2020 01:27:56
User entered 'No (N)'	System	12 Sep 2020 01:27:56

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-11T21:27:51', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '327176bb-4fc4-4b4e-ae4c-71fa7e3b9771'	System	12 Sep 2020 01:27:56
User entered '11 Sep 2020 21:27'	System	12 Sep 2020 01:27:56

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 3'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-12T18:16:24', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2931face-72ec-45ac-b307-10d5ddefdb43'	System	12 Sep 2020 22:16:52
User entered 'None (0)'	System	12 Sep 2020 22:16:52

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-12T18:16:27', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2931face-72ec-45ac-b307-10d5ddefdb43'	System	12 Sep 2020 22:16:52
User entered 'None (0)'	System	12 Sep 2020 22:16:52

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-12T18:16:31', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2931face-72ec-45ac-b307-10d5ddefdb43'	System	12 Sep 2020 22:16:52
User entered 'None (0)'	System	12 Sep 2020 22:16:52

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-12T18:16:34', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2931face-72ec-45ac-b307-10d5ddefdb43'	System	12 Sep 2020 22:16:52
User entered 'None (0)'	System	12 Sep 2020 22:16:52

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-12T18:16:37', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2931face-72ec-45ac-b307-10d5ddefdb43'	System	12 Sep 2020 22:16:52
User entered 'None (0)'	System	12 Sep 2020 22:16:52

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-12T18:16:40', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2931face-72ec-45ac-b307-10d5ddefdb43'	System	12 Sep 2020 22:16:52
User entered 'None (0)'	System	12 Sep 2020 22:16:52

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-12T18:16:44', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2931face-72ec-45ac-b307-10d5ddefdb43'	System	12 Sep 2020 22:16:52
User entered 'No (N)'	System	12 Sep 2020 22:16:52

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-12T18:16:48', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2931face-72ec-45ac-b307-10d5ddefdb43'	System	12 Sep 2020 22:16:52
User entered '12 Sep 2020 18:16'	System	12 Sep 2020 22:16:52

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 4'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 5'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 6'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-15T13:23:04', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'e4719b0d-e0ee-46e5-a758-852159d3700e'	System	15 Sep 2020 17:23:40
User entered 'None (0)'	System	15 Sep 2020 17:23:40

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-15T13:23:13', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'e4719b0d-e0ee-46e5-a758-852159d3700e'	System	15 Sep 2020 17:23:40
User entered 'None (0)'	System	15 Sep 2020 17:23:40

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-15T13:23:16', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'e4719b0d-e0ee-46e5-a758-852159d3700e'	System	15 Sep 2020 17:23:40
User entered 'None (0)'	System	15 Sep 2020 17:23:40

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-15T13:23:18', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'e4719b0d-e0ee-46e5-a758-852159d3700e'	System	15 Sep 2020 17:23:40
User entered 'None (0)'	System	15 Sep 2020 17:23:40

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-15T13:23:23', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'e4719b0d-e0ee-46e5-a758-852159d3700e'	System	15 Sep 2020 17:23:40
User entered 'None (0)'	System	15 Sep 2020 17:23:40

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-15T13:23:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'e4719b0d-e0ee-46e5-a758-852159d3700e'	System	15 Sep 2020 17:23:40
User entered 'None (0)'	System	15 Sep 2020 17:23:40

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-15T13:23:29', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'e4719b0d-e0ee-46e5-a758-852159d3700e'	System	15 Sep 2020 17:23:40
User entered 'No (N)'	System	15 Sep 2020 17:23:40

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-09-15T13:23:32', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'e4719b0d-e0ee-46e5-a758-852159d3700e' User entered '15 Sep 2020 13:23'	System	15 Sep 2020 17:23:40
	System	15 Sep 2020 17:23:40

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	10 Sep 2020 15:27:57
User entered 'Day 7'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:27:57

US3222117

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:02:02

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:27:57

US3222117

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:47:29

US3222117

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '17 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:47:29

US3222117

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:47:29

US3222117

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:47:29

US3222117

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:47:40

US3222117

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '1'	System	07 Oct 2020 16:47:40

US3222117

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:47:54

US3222117

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '24 Sep 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:47:54

US3222117

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:47:54

US3222117

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:47:54

US3222117

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:48:02

US3222117

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '1'	System	07 Oct 2020 16:48:02

US3222117

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:48:19

US3222117

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '1 Oct 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:48:19

US3222117

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:48:19

US3222117

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:48:19

US3222117

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:48:22

US3222117

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '1'	System	07 Oct 2020 16:48:22

US3222117

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:49:51

US3222117

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '7 Oct 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:49:51

US3222117

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Clinic (Clinic)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:49:51

US3222117

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered 'VISIT3'	System	07 Oct 2020 16:49:51

US3222117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:49:58

US3222117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:49:58

US3222117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:49:58

US3222117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered empty.	System	07 Oct 2020 16:49:58

US3222117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:49:58

US3222117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:49:58

US3222117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:49:58

US3222117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:49:58

US3222117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered empty.	System	07 Oct 2020 16:49:58

US3222117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:49:58

US3222117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered empty.	System	07 Oct 2020 16:49:58

US3222117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:49:58

US3222117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered empty.	System	07 Oct 2020 16:49:58

US3222117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:49:58

US3222117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered empty.	System	07 Oct 2020 16:49:58

US3222117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25

US3222117

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25

US3222117

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:50:01

US3222117

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:50:01

US3222117

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:50:11

US3222117

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '7 Oct 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:50:11

US3222117

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '10:45'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:50:11

US3222117

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '7 Oct 2020 10:45'	System	07 Oct 2020 16:50:11

US3222117

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:50:15

US3222117

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '1'	System	07 Oct 2020 16:50:15

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 64'	System	12 Aug 2020 20:53:39

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-10-16T14:55:43', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '7383f04f-0707-4f70-919d-29824f0093fa'	System	16 Oct 2020 18:56:10
User entered 'No (N)'	System	16 Oct 2020 18:56:10

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-10-16T14:55:50', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '7383f04f-0707-4f70-919d-29824f0093fa'	System	16 Oct 2020 18:56:10
User entered 'No (N)'	System	16 Oct 2020 18:56:10

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-10-16T14:56:04', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '7383f04f-0707-4f70-919d-29824f0093fa' User entered '16 Oct 2020 14:56:04'	System	16 Oct 2020 18:56:10
	System	16 Oct 2020 18:56:10

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered '12 Oct 2020 00:01'	System	12 Aug 2020 20:53:39

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered '16 Oct 2020 23:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 71'	System	12 Aug 2020 20:53:39

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-10-19T10:23:56', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '64dfeb30-00cf-44a3-9f42-fb72e5647025'	System	19 Oct 2020 14:24:12
User entered 'No (N)'	System	19 Oct 2020 14:24:12

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-10-19T10:24:01', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '64dfeb30-00cf-44a3-9f42-fb72e5647025'	System	19 Oct 2020 14:24:12
User entered 'No (N)'	System	19 Oct 2020 14:24:12

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-10-19T10:24:06', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '64dfeb30-00cf-44a3-9f42-fb72e5647025' User entered '19 Oct 2020 10:24:06'	System	19 Oct 2020 14:24:12
	System	19 Oct 2020 14:24:12

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered '19 Oct 2020 00:01'	System	12 Aug 2020 20:53:39

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered '23 Oct 2020 23:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 78'	System	12 Aug 2020 20:53:39

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-10-26T09:59:47', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '33ea0a18-0ca9-4b89-a41d-845b8624ffa1'	System	26 Oct 2020 14:00:22
User entered 'No (N)'	System	26 Oct 2020 14:00:22

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-10-26T09:59:57', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '33ea0a18-0ca9-4b89-a41d-845b8624ffa1'	System	26 Oct 2020 14:00:22
User entered 'No (N)'	System	26 Oct 2020 14:00:22

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-10-26T10:00:16', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '33ea0a18-0ca9-4b89-a41d-845b8624ffa1' User entered '26 Oct 2020 10:00:16'	System	26 Oct 2020 14:00:22
	System	26 Oct 2020 14:00:22

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered '26 Oct 2020 00:01'	System	12 Aug 2020 20:53:39

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered '30 Oct 2020 23:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 92'	System	12 Aug 2020 20:53:39

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-09T09:01:15', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'bc81b060-32e6-47b7-a83d-05bfb5d2654b'	System	09 Nov 2020 14:01:38
User entered 'No (N)'	System	09 Nov 2020 14:01:38

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-09T09:01:22', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'bc81b060-32e6-47b7-a83d-05bfb5d2654b'	System	09 Nov 2020 14:01:38
User entered 'No (N)'	System	09 Nov 2020 14:01:38

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-09T09:01:34', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'bc81b060-32e6-47b7-a83d-05bfb5d2654b'	System	09 Nov 2020 14:01:38
User entered '09 Nov 2020 09:01:34'	System	09 Nov 2020 14:01:38

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered '09 Nov 2020 00:01'	System	12 Aug 2020 20:53:39

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered '13 Nov 2020 23:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered 'Day 99'	System	12 Aug 2020 20:53:39

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:45:14', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c'	System	16 Nov 2020 13:47:04
User entered 'Yes (Y)'	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with 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)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:45:29', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c'	System	16 Nov 2020 13:47:04
User entered 'Yes (Y)'	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Please 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)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:45:45', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c'	System	16 Nov 2020 13:47:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:45:52', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c'	System	16 Nov 2020 13:47:04
User entered 'Yes (Y)'	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c' User entered '1'	System	16 Nov 2020 13:47:04
	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c' User entered '0'	System	16 Nov 2020 13:47:04
	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c' User entered '1'	System	16 Nov 2020 13:47:04
	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c'	System	16 Nov 2020 13:47:04
User entered '1'	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c' User entered '1'	System	16 Nov 2020 13:47:04
	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c' User entered '0'	System	16 Nov 2020 13:47:04
	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c' User entered '1'	System	16 Nov 2020 13:47:04
	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c' User entered '1'	System	16 Nov 2020 13:47:04
	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c'	System	16 Nov 2020 13:47:04
User entered '1'	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c' User entered '1'	System	16 Nov 2020 13:47:04
	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c' User entered '1'	System	16 Nov 2020 13:47:04
	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c' User entered '0'	System	16 Nov 2020 13:47:04
	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c' User entered '1'	System	16 Nov 2020 13:47:04
	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c' User entered '1'	System	16 Nov 2020 13:47:04
	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c'	System	16 Nov 2020 13:47:04
User entered '0'	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c' User entered '0'	System	16 Nov 2020 13:47:04
	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c' User entered '1'	System	16 Nov 2020 13:47:04
	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Please 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)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:31', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c'	System	16 Nov 2020 13:47:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

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)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:41', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c'	System	16 Nov 2020 13:47:04
User entered 'No (N)'	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-16T08:46:50', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '6e5c0315-c95b-40aa-ae90-7ab1ae0dda0c'	System	16 Nov 2020 13:47:04
User entered '16 Nov 2020 08:46:50'	System	16 Nov 2020 13:47:04

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered '16 Nov 2020 00:01'	System	12 Aug 2020 20:53:39

US3222117

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 01:18:43
Data entry locked.	System	12 Aug 2020 20:53:39
User entered '20 Nov 2020 23:59'	System	12 Aug 2020 20:53:39

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-20T07:35:07', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '12bfd08f-faca-4f40-a3c9-4cfc90709a72'	System	20 Nov 2020 12:35:46
User entered 'No (N)'	System	20 Nov 2020 12:35:46

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-20T07:35:14', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '12bfd08f-faca-4f40-a3c9-4cfc90709a72'	System	20 Nov 2020 12:35:46
User entered 'Yes (Y)'	System	20 Nov 2020 12:35:46

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-20T07:35:22', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '12bfd08f-faca-4f40-a3c9-4cfc90709a72'	System	20 Nov 2020 12:35:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Nov 2020 12:35:46

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-20T07:35:32', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '12bfd08f-faca-4f40-a3c9-4cfc90709a72'	System	20 Nov 2020 12:35:46
User entered '20 Nov 2020 07:35:32'	System	20 Nov 2020 12:35:46

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-27T07:48:02', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '128d79cb-1589-4049-be4e-b0246dc0e8b8'	System	27 Nov 2020 12:48:29
User entered 'No (N)'	System	27 Nov 2020 12:48:29

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-27T07:48:08', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '128d79cb-1589-4049-be4e-b0246dc0e8b8'	System	27 Nov 2020 12:48:29
User entered 'Yes (Y)'	System	27 Nov 2020 12:48:29

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-27T07:48:11', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '128d79cb-1589-4049-be4e-b0246dc0e8b8'	System	27 Nov 2020 12:48:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Nov 2020 12:48:29

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-11-27T07:48:18', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '128d79cb-1589-4049-be4e-b0246dc0e8b8'	System	27 Nov 2020 12:48:29
User entered '27 Nov 2020 07:48:18'	System	27 Nov 2020 12:48:29

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-06T10:17:34', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '84541413-82a4-45b5-98da-1a5e53e95bde'	System	06 Dec 2020 15:18:34
User entered 'Yes (Y)'	System	06 Dec 2020 15:18:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-06T10:17:41', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '84541413-82a4-45b5-98da-1a5e53e95bde'	System	06 Dec 2020 15:18:34
User entered 'No (N)'	System	06 Dec 2020 15:18:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-06T10:17:55', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '84541413-82a4-45b5-98da-1a5e53e95bde'	System	06 Dec 2020 15:18:34
User entered 'No (N)'	System	06 Dec 2020 15:18:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-06T10:18:05', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '84541413-82a4-45b5-98da-1a5e53e95bde'	System	06 Dec 2020 15:18:34
User entered 'Yes (Y)'	System	06 Dec 2020 15:18:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-06T10:18:11', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '84541413-82a4-45b5-98da-1a5e53e95bde'	System	06 Dec 2020 15:18:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Dec 2020 15:18:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-06T10:18:19', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '84541413-82a4-45b5-98da-1a5e53e95bde'	System	06 Dec 2020 15:18:34
User entered '06 Dec 2020 10:18:19'	System	06 Dec 2020 15:18:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-11T08:30:18', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '210399b3-33c7-45f7-838d-c970ab8e02e7'	System	11 Dec 2020 13:33:26
User entered 'Yes (Y)'	System	11 Dec 2020 13:33:26

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-11T08:30:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '210399b3-33c7-45f7-838d-c970ab8e02e7'	System	11 Dec 2020 13:33:26
User entered 'No (N)'	System	11 Dec 2020 13:33:26

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-11T08:30:34', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '210399b3-33c7-45f7-838d-c970ab8e02e7'	System	11 Dec 2020 13:33:26
User entered 'No (N)'	System	11 Dec 2020 13:33:26

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-11T08:30:43', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '210399b3-33c7-45f7-838d-c970ab8e02e7'	System	11 Dec 2020 13:33:26
User entered 'Yes (Y)'	System	11 Dec 2020 13:33:26

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-11T08:30:49', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '210399b3-33c7-45f7-838d-c970ab8e02e7'	System	11 Dec 2020 13:33:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Dec 2020 13:33:26

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-11T08:30:54', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '210399b3-33c7-45f7-838d-c970ab8e02e7'	System	11 Dec 2020 13:33:26
User entered '11 Dec 2020 08:30:54'	System	11 Dec 2020 13:33:26

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-19T09:23:24', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'abf8ecbe-4736-47f4-84c9-3b935c64d7d9'	System	19 Dec 2020 14:23:53
User entered 'Yes (Y)'	System	19 Dec 2020 14:23:53

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-19T09:23:28', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'abf8ecbe-4736-47f4-84c9-3b935c64d7d9'	System	19 Dec 2020 14:23:53
User entered 'No (N)'	System	19 Dec 2020 14:23:53

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-19T09:23:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'abf8ecbe-4736-47f4-84c9-3b935c64d7d9'	System	19 Dec 2020 14:23:53
User entered 'No (N)'	System	19 Dec 2020 14:23:53

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-19T09:23:44', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'abf8ecbe-4736-47f4-84c9-3b935c64d7d9'	System	19 Dec 2020 14:23:53
User entered 'No (N)'	System	19 Dec 2020 14:23:53

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-19T09:23:49', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'abf8ecbe-4736-47f4-84c9-3b935c64d7d9'	System	19 Dec 2020 14:23:53
User entered '19 Dec 2020 09:23:49'	System	19 Dec 2020 14:23:53

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-25T08:38:47', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ce2c650f-12ed-4815-be41-6cf8fa095890'	System	25 Dec 2020 13:39:15
User entered 'Yes (Y)'	System	25 Dec 2020 13:39:15

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-25T08:38:50', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ce2c650f-12ed-4815-be41-6cf8fa095890'	System	25 Dec 2020 13:39:15
User entered 'No (N)'	System	25 Dec 2020 13:39:15

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-25T08:38:54', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ce2c650f-12ed-4815-be41-6cf8fa095890'	System	25 Dec 2020 13:39:15
User entered 'No (N)'	System	25 Dec 2020 13:39:15

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-25T08:39:02', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ce2c650f-12ed-4815-be41-6cf8fa095890'	System	25 Dec 2020 13:39:15
User entered 'No (N)'	System	25 Dec 2020 13:39:15

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2020-12-25T08:39:06', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ce2c650f-12ed-4815-be41-6cf8fa095890'	System	25 Dec 2020 13:39:15
User entered '25 Dec 2020 08:39:06'	System	25 Dec 2020 13:39:15

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:06:49', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered 'Yes (Y)'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered 'No (N)'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:10', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered 'Yes (Y)'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered '0'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered '0'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered '0'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered '0'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered '1'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered '0'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered '0'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered '0'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered '0'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered '0'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered '0'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered '0'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered '0'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered '0'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered '0'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered '0'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered '0'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:40', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:48', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered 'No (N)'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-01T03:07:54', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '88bf8401-c92f-4683-be76-d4b477d86d9c'	System	01 Jan 2021 08:08:05
User entered '01 Jan 2021 03:07:54'	System	01 Jan 2021 08:08:05

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-08T04:01:33', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'f76c07b8-496a-4f69-b7f7-aa214758337e'	System	08 Jan 2021 09:02:10
User entered 'No (N)'	System	08 Jan 2021 09:02:10

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-08T04:01:45', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'f76c07b8-496a-4f69-b7f7-aa214758337e'	System	08 Jan 2021 09:02:10
User entered 'No (N)'	System	08 Jan 2021 09:02:10

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-08T04:02:06', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'f76c07b8-496a-4f69-b7f7-aa214758337e'	System	08 Jan 2021 09:02:10
User entered '08 Jan 2021 04:02:06'	System	08 Jan 2021 09:02:10

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:12:43', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered 'Yes (Y)'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:12:49', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered 'No (N)'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:04', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered 'Yes (Y)'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered '0'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered '0'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered '1'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered '1'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered '1'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered '1'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered '0'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered '0'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered '1'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered '0'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered '0'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered '0'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered '0'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered '0'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered '0'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered '0'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:25', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered '0'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:29', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:42', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered 'Yes (Y)'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Please contact your study clinic immediately. [Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:47', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-15T05:13:54', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '55f23c86-4a95-4b1a-a607-0cfbd000ab54'	System	15 Jan 2021 10:14:08
User entered '15 Jan 2021 05:13:54'	System	15 Jan 2021 10:14:08

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-22T09:39:03', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'bd240708-d68d-48f9-8df6-736b970d7e1a'	System	22 Jan 2021 14:39:16
User entered 'No (N)'	System	22 Jan 2021 14:39:16

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-22T09:39:06', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'bd240708-d68d-48f9-8df6-736b970d7e1a'	System	22 Jan 2021 14:39:16
User entered 'No (N)'	System	22 Jan 2021 14:39:16

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-22T09:39:10', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'bd240708-d68d-48f9-8df6-736b970d7e1a'	System	22 Jan 2021 14:39:16
User entered '22 Jan 2021 09:39:10'	System	22 Jan 2021 14:39:16

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-29T06:51:31', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '22f54f89-1c94-4fbf-ba88-1d196b23b014'	System	29 Jan 2021 11:51:52
User entered 'No (N)'	System	29 Jan 2021 11:51:52

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-29T06:51:42', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '22f54f89-1c94-4fbf-ba88-1d196b23b014'	System	29 Jan 2021 11:51:52
User entered 'No (N)'	System	29 Jan 2021 11:51:52

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-01-29T06:51:48', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '22f54f89-1c94-4fbf-ba88-1d196b23b014'	System	29 Jan 2021 11:51:52
User entered '29 Jan 2021 06:51:48'	System	29 Jan 2021 11:51:52

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-02-05T10:34:32', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'b16ec163-f815-4b3d-a4c4-3e7873f03c6b'	System	05 Feb 2021 15:34:46
User entered 'No (N)'	System	05 Feb 2021 15:34:46

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-02-05T10:34:36', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'b16ec163-f815-4b3d-a4c4-3e7873f03c6b'	System	05 Feb 2021 15:34:46
User entered 'No (N)'	System	05 Feb 2021 15:34:46

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-02-05T10:34:40', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'b16ec163-f815-4b3d-a4c4-3e7873f03c6b'	System	05 Feb 2021 15:34:46
User entered '05 Feb 2021 10:34:40'	System	05 Feb 2021 15:34:46

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-02-12T11:03:43', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '0921f558-b882-4ddb-b59a-adc046f873e2'	System	12 Feb 2021 16:03:57
User entered 'No (N)'	System	12 Feb 2021 16:03:57

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-02-12T11:03:47', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '0921f558-b882-4ddb-b59a-adc046f873e2'	System	12 Feb 2021 16:03:57
User entered 'No (N)'	System	12 Feb 2021 16:03:57

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-02-12T11:03:51', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '0921f558-b882-4ddb-b59a-adc046f873e2'	System	12 Feb 2021 16:03:57
User entered '12 Feb 2021 11:03:51'	System	12 Feb 2021 16:03:57

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-02-19T07:58:16', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '3f751dbc-56c2-4b55-85e0-ae576b6aa049'	System	19 Feb 2021 12:58:27
User entered 'No (N)'	System	19 Feb 2021 12:58:27

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-02-19T07:58:20', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '3f751dbc-56c2-4b55-85e0-ae576b6aa049'	System	19 Feb 2021 12:58:27
User entered 'No (N)'	System	19 Feb 2021 12:58:27

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-02-19T07:58:24', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '3f751dbc-56c2-4b55-85e0-ae576b6aa049'	System	19 Feb 2021 12:58:27
User entered '19 Feb 2021 07:58:24'	System	19 Feb 2021 12:58:27

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-02-26T06:30:19-05:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '3798c6f2-3e20-4a30-aa9b-3b94ef88f531'	System	26 Feb 2021 11:30:30
User entered 'No (N)'	System	26 Feb 2021 11:30:30

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-02-26T06:30:23-05:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '3798c6f2-3e20-4a30-aa9b-3b94ef88f531'	System	26 Feb 2021 11:30:30
User entered 'No (N)'	System	26 Feb 2021 11:30:30

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-02-26T06:30:26-05:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '3798c6f2-3e20-4a30-aa9b-3b94ef88f531'	System	26 Feb 2021 11:30:30
User entered '26 Feb 2021 06:30:26'	System	26 Feb 2021 11:30:30

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-03-05T05:56:42-05:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '896d2ba7-d614-4c8c-a48d-770be4a4087b'	System	05 Mar 2021 10:56:58
User entered 'No (N)'	System	05 Mar 2021 10:56:58

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-03-05T05:56:48-05:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '896d2ba7-d614-4c8c-a48d-770be4a4087b'	System	05 Mar 2021 10:56:58
User entered 'No (N)'	System	05 Mar 2021 10:56:58

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-03-05T05:56:53-05:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '896d2ba7-d614-4c8c-a48d-770be4a4087b' User entered '05 Mar 2021 05:56:53'	System	05 Mar 2021 10:56:58

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-03-13T06:55:54-05:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '9fcee714-4600-42ca-b72a-b6cd4d7ca236'	System	13 Mar 2021 11:56:15
User entered 'No (N)'	System	13 Mar 2021 11:56:15

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-03-13T06:56:07-05:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '9fcee714-4600-42ca-b72a-b6cd4d7ca236'	System	13 Mar 2021 11:56:15
User entered 'No (N)'	System	13 Mar 2021 11:56:15

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-03-13T06:56:11-05:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '9fcee714-4600-42ca-b72a-b6cd4d7ca236'	System	13 Mar 2021 11:56:15
User entered '13 Mar 2021 06:56:11'	System	13 Mar 2021 11:56:15

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-03-19T06:15:36-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '4303dbb8-e1c4-45e6-8bd2-99e66158ca45'	System	19 Mar 2021 10:15:48
User entered 'No (N)'	System	19 Mar 2021 10:15:48

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-03-19T06:15:40-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '4303dbb8-e1c4-45e6-8bd2-99e66158ca45'	System	19 Mar 2021 10:15:48
User entered 'No (N)'	System	19 Mar 2021 10:15:48

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-03-19T06:15:43-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '4303dbb8-e1c4-45e6-8bd2-99e66158ca45'	System	19 Mar 2021 10:15:48
User entered '19 Mar 2021 06:15:43'	System	19 Mar 2021 10:15:48

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-03-26T06:11:38-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2a332cad-55b3-44e4-8f08-4aac59f807ef' User entered 'No (N)'	System	26 Mar 2021 10:11:57
	System	26 Mar 2021 10:11:57

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-03-26T06:11:48-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2a332cad-55b3-44e4-8f08-4aac59f807ef'	System	26 Mar 2021 10:11:57
User entered 'No (N)'	System	26 Mar 2021 10:11:57

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-03-26T06:11:51-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '2a332cad-55b3-44e4-8f08-4aac59f807ef' User entered '26 Mar 2021 06:11:51'	System	26 Mar 2021 10:11:57
	System	26 Mar 2021 10:11:57

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-04-02T09:42:05-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ca6114c5-b185-44fc-8a39-0ab1cb803a20'	System	02 Apr 2021 13:42:21
User entered 'No (N)'	System	02 Apr 2021 13:42:21

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-04-02T09:42:10-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ca6114c5-b185-44fc-8a39-0ab1cb803a20'	System	02 Apr 2021 13:42:21
User entered 'No (N)'	System	02 Apr 2021 13:42:21

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-04-02T09:42:16-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'ca6114c5-b185-44fc-8a39-0ab1cb803a20'	System	02 Apr 2021 13:42:21
User entered '02 Apr 2021 09:42:16'	System	02 Apr 2021 13:42:21

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-04-10T17:38:33-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'fd1777c6-c246-4f24-819a-da8c6dca77a5'	System	10 Apr 2021 21:38:54
User entered 'No (N)'	System	10 Apr 2021 21:38:54

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-04-10T17:38:37-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'fd1777c6-c246-4f24-819a-da8c6dca77a5'	System	10 Apr 2021 21:38:54
User entered 'No (N)'	System	10 Apr 2021 21:38:54

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-04-10T17:38:40-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'fd1777c6-c246-4f24-819a-da8c6dca77a5'	System	10 Apr 2021 21:38:54
User entered '10 Apr 2021 17:38:40'	System	10 Apr 2021 21:38:54

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-04-16T09:37:32-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '634a82db-d897-4d83-97a7-4343856fd459'	System	16 Apr 2021 13:37:43
User entered 'No (N)'	System	16 Apr 2021 13:37:43

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-04-16T09:37:36-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '634a82db-d897-4d83-97a7-4343856fd459'	System	16 Apr 2021 13:37:43
User entered 'No (N)'	System	16 Apr 2021 13:37:43

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-04-16T09:37:39-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '634a82db-d897-4d83-97a7-4343856fd459'	System	16 Apr 2021 13:37:43
User entered '16 Apr 2021 09:37:39'	System	16 Apr 2021 13:37:43

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-04-23T07:39:47-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'a417b95b-9d7a-4017-8b80-8f175d735637'	System	23 Apr 2021 11:40:00
User entered 'No (N)'	System	23 Apr 2021 11:40:00

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-04-23T07:39:49-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'a417b95b-9d7a-4017-8b80-8f175d735637'	System	23 Apr 2021 11:40:00
User entered 'No (N)'	System	23 Apr 2021 11:40:00

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-04-23T07:39:52-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'a417b95b-9d7a-4017-8b80-8f175d735637'	System	23 Apr 2021 11:40:00
User entered '23 Apr 2021 07:39:52'	System	23 Apr 2021 11:40:00

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-04-30T06:25:24-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '08dc392a-c063-4a90-bbec-81dd8ef5d223'	System	30 Apr 2021 10:25:38
User entered 'No (N)'	System	30 Apr 2021 10:25:38

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-04-30T06:25:27-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '08dc392a-c063-4a90-bbec-81dd8ef5d223'	System	30 Apr 2021 10:25:38
User entered 'No (N)'	System	30 Apr 2021 10:25:38

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-04-30T06:25:29-04:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: '08dc392a-c063-4a90-bbec-81dd8ef5d223'	System	30 Apr 2021 10:25:38
User entered '30 Apr 2021 06:25:29'	System	30 Apr 2021 10:25:38

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 05:27:34

US3222117

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:02:02

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 05:27:34
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 05:27:34

US3222117

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:02:02

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:20:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-02-27T13:00:35-05:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'b341afdf-730e-4558-8753-9285770e2aa1'	System	27 Feb 2021 18:00:52
User entered 'No (N)'	System	27 Feb 2021 18:00:52

US3222117

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:02:02

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:20:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95b44098aec5848c)', Time: '2021-02-27T13:00:39-05:00', User OID: 'PatientReportedOutcome (US3222117)', ODM File OID: 'b341afdf-730e-4558-8753-9285770e2aa1' User entered '27 Feb 2021 13:00:39'	System	27 Feb 2021 18:00:52
	System	27 Feb 2021 18:00:52

US3222117

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	04 Nov 2020 20:16:59

US3222117

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '4 Nov 2020'	(b) (4) Albert Garcia (b) (4) (b) (4)	04 Nov 2020 20:16:59

US3222117

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4) (b) (4)	04 Nov 2020 20:16:59

US3222117

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	04 Nov 2020 20:16:59

US3222117

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per GCL Lab Reconciliation: Saliva: Per GCL, there is a Saliva sample with a Collection Date of 17DEC2020 recorded under Convalescence Visit Day 28, however, per Viracor, the Saliva sample with a Collection Date of 17DEC2020 is recorded under an Unscheduled Visit. Please confirm the correct Visit Name in the query response, as appropriate. This sample is also missing in EDC. If this sample was collected, please record the data in the appropriate folder.' (Site from DM). Query 'Per GCL Lab Reconciliation: Saliva: Per GCL, there is a Saliva sample with a Collection Date of 17DEC2020 recorded under Convalescence Visit Day 28, however, per Viracor, the Saliva sample with a Collection Date of 17DEC2020 is recorded under an Unscheduled Visit. Please confirm the correct Visit Name in the query response, as appropriate. This sample is also missing in EDC. If this sample was collected, please record the data in the appropriate folder.' answered with '17-DEC-2020 IS DAY 28 AND NOT UNSCHEDULED.' (Site from DM).	(b) (4) (b) (4), (b) (6) douglas winter (b) (4) (b) (4)	19 Feb 2021 11:24:54 19 Feb 2021 02:31:56
User opened query 'Per GCL Lab Reconciliation: Saliva: Per GCL, there is a Saliva sample with a Collection Date of 17DEC2020 recorded under Convalescence Visit Day 28, however, per Viracor, the Saliva sample with a Collection Date of 17DEC2020 is recorded under an Unscheduled Visit. Please confirm the correct Visit Name in the query response, as appropriate. This sample is also missing in EDC. If this sample was collected, please record the data in the appropriate folder.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 20:54:35
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	04 Nov 2020 20:16:47

US3222117

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 18:06:25
User entered '1'	System	04 Nov 2020 20:16:47

US3222117

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 14:25:20

US3222117

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 14:16:46
User signature succeeded.	Bruce Rankin (b) (4) [REDACTED]	19 Feb 2021 16:11:03
User entered '09 Dec 2020'	(b) (4) (b) (4), (b) (6) [REDACTED]	09 Feb 2021 14:25:20

US3222117

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 14:25:20

US3222117

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 14:25:20

US3222117

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 14:25:26

US3222117

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User entered '1'	System	09 Feb 2021 14:25:26

US3222117

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 14:25:49

US3222117

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered '08 Jan 2021'	(b) (4), (b) (6)	09 Feb 2021 14:25:49

US3222117

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Feb 2021 14:25:49

US3222117

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 14:16:46
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4), (b) (6) [REDACTED]	09 Feb 2021 14:25:49

US3222117

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 14:25:54

US3222117

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User entered '1'	System	09 Feb 2021 14:25:54

US3222117

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
	(b) (4)	
Signature has been broken. (WR# 5303595)	System	12 Apr 2021 18:13:34
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:36:04
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 22:18:14

US3222117

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
	(b) (4)	
Signature has been broken. (WR# 5303595)	System	12 Apr 2021 18:13:34
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:36:04
	(b) (4)	
User entered '7 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 22:18:14

US3222117

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
	(b) (4)	
Signature has been broken. (WR# 5303595)	System	12 Apr 2021 18:13:34
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:36:04
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Feb 2021 22:18:14

US3222117

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
	(b) (4)	
Signature has been broken. (WR# 5303595)	System	12 Apr 2021 18:13:34
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:36:04
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 22:18:14

US3222117

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
	(b) (4)	
Signature has been broken. (WR# 5303595)	System	12 Apr 2021 18:13:34
User signature succeeded.	Vicki Miller (b) (4)	26 Feb 2021 21:36:04
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 22:18:18

US3222117

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:16:46
User entered '1'	System	25 Feb 2021 22:18:18

US3222117

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	12 Apr 2021 18:13:34
	Vicki Miller (b) (4)	26 Feb 2021 21:36:04
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 22:18:29

US3222117

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	12 Apr 2021 18:13:34
	Vicki Miller (b) (4)	26 Feb 2021 21:36:04
User entered '25 Feb 2021'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 22:18:29

US3222117

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	12 Apr 2021 18:13:34
	Vicki Miller (b) (4)	26 Feb 2021 21:36:04
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Feb 2021 22:18:29

US3222117

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User entered 'VISIT4'	System	25 Feb 2021 22:18:29

US3222117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:48:11

US3222117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:48:11

US3222117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:48:11

US3222117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User entered empty.	System	31 Mar 2021 12:48:11

US3222117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:48:11

US3222117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:48:11

US3222117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:48:11

US3222117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:48:11

US3222117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User entered empty.	System	31 Mar 2021 12:48:11

US3222117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:48:11

US3222117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User entered empty.	System	31 Mar 2021 12:48:11

US3222117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:48:11

US3222117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User entered empty.	System	31 Mar 2021 12:48:11

US3222117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:48:11

US3222117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User entered empty.	System	31 Mar 2021 12:48:11

US3222117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41

US3222117

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41

US3222117

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	12 Apr 2021 18:13:34
	Vicki Miller (b) (4)	26 Feb 2021 21:36:04
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 22:18:36

US3222117

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	12 Apr 2021 18:13:34
	Vicki Miller (b) (4)	26 Feb 2021 21:36:04
	(b) (4)	
User entered '25 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 22:18:36

US3222117

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 13:48:13
User entered 'Yes (Y)'	Crystal Paccione (b) (4) (b) (4)	25 Mar 2021 18:50:58

US3222117

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	25 Mar 2021 18:51:29
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	25 Mar 2021 18:51:29
User entered '25 Feb 2021' reason for change: Data Entry Error	Crystal Paccione (b) (4)	25 Mar 2021 18:51:29
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	25 Mar 2021 18:50:58
User entered '15 Feb 2021'	System	25 Mar 2021 18:50:58
	Crystal Paccione (b) (4)	25 Mar 2021 18:50:58
	(b) (4)	

US3222117

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User entered '11:15'	(b) (4) Crystal Paccione (b) (4)	25 Mar 2021 18:50:58

US3222117

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User entered '25 Feb 2021 11:15'	System	25 Mar 2021 18:51:29
User entered '15 Feb 2021 11:15'	System	25 Mar 2021 18:50:58

US3222117

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Signature has been broken. (WR# 5303595)	(b) (4)	12 Apr 2021 18:13:34
User signature succeeded.	System	12 Apr 2021 18:13:34
	Vicki Miller (b) (4)	26 Feb 2021 21:36:04
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 22:18:40

US3222117

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 10:30:41
User entered '1'	System	25 Feb 2021 22:18:40

US3222117

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:00:19

US3222117

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User entered '07 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:00:19

US3222117

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:00:19

US3222117

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:02:02

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:00:19

US3222117

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:00:26

US3222117

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:02:02

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 14:00:26

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:02:02

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:07
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:22
User entered '17 Nov 2020'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:28:57

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:02:02

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:07
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:22
User entered '08:50'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:28:57

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:02:02

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:07
User entered '17 Nov 2020 08:50'	System	17 Nov 2020 15:28:57

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:02:02

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:07
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:22
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	-douglas winter (b) (4) (b) (4)	17 Nov 2020 15:28:57

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:02:02

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:07
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:22
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:28:57

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 1 (Day 1)'	(b) (4) douglas winter (b) (4)	17 Nov 2020 15:32:48

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User closed query 'Please verify if this was the first date subject experienced symptoms. If not, please add additional lines with dates since subject first experienced symptoms per CCGs. ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:18:22
Query 'Please verify if this was the first date subject experienced symptoms. If not, please add additional lines with dates since subject first experienced symptoms per CCGs. ' answered with 'ONSET OF SYMPTOMS WAS 13/NOV AND THE SYMPTOMS REMAINED THE SAME UNTIL HE GOT INTO THE CLINIC ON 17/NOV.' (Site from CRA).	douglas winter (b) (4) (b) (4)	23 Nov 2020 13:55:57
User entered '13 Nov 2020' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Nov 2020 13:54:39
User opened query 'Please verify if this was the first date subject experienced symptoms. If not, please add additional lines with dates since subject first experienced symptoms per CCGs. ' (Site from CRA).	(b) (4), (b) (6)	21 Nov 2020 16:55:54
User entered '17 Nov 2020'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:32:48

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:39:26
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered '0' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User closed query 'Per CDM: Assessment Not Done is checked however, Assessment Not Done should only be selected if the entire assessment was empty. Please review/update accordingly, Else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 12:08:43
Query 'Per CDM: Assessment Not Done is checked however, Assessment Not Done should only be selected if the entire assessment was empty. Please review/update accordingly, Else clarify. Thank you.' answered with 'Assessment was not done so it is marked as not done' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	25 Feb 2021 14:25:20
User opened query 'Per CDM: Assessment Not Done is checked however, Assessment Not Done should only be selected if the entire assessment was empty. Please review/update accordingly, Else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:06:24
User closed query 'Per CDM: Assessment Not Done is checked however, there is data present on this form for O2 Saturation and Temperature? Assessment Not Done should only be selected if the entire assessment was not completed. Please review/update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:06:24
Query 'Per CDM: Assessment Not Done is checked however, there is data present on this form for O2 Saturation and Temperature? Assessment Not Done should only be selected if the entire assessment was not completed. Please review/update accordingly. Thank you.' answered with 'subject did not complete this entr' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	24 Feb 2021 19:33:12

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Assessment Not Done is checked however, there is data present on this form for O2 Saturation and Temperature? Assessment Not Done should only be selected if the entire assessment was not completed. Please review/update accordingly. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	23 Feb 2021 09:24:33
DataPoint Verified.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:10
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '0'	douglas winter (b) (4)	17 Nov 2020 15:32:48

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:39:26
User entered missing code ND - Not Done; reason for change Data Entry Error	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
User closed query 'Per CDM: Please remove Not Done at O2 Saturation and Temperature as Assessment Not Done is checked for days 1-4. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 12:29:57
Query 'Per CDM: Please remove Not Done at O2 Saturation and Temperature as Assessment Not Done is checked for days 1-4. ' answered with 'O2 saturation and temperature "ND" removed for days 1-4' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 18:50:51
DataPoint Un-verified.	(b) (4), (b) (6)	27 Feb 2021 18:49:05
Signature has been broken.	(b) (4), (b) (6)	27 Feb 2021 18:49:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Feb 2021 18:49:05
User opened query 'Per CDM: Please remove Not Done at O2 Saturation and Temperature as Assessment Not Done is checked for days 1-4. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 12:14:44
User closed query 'Per CDM: Assessment Not Done is checked however, there is data present on this form? Assessment Not Done should only be selected if the entire assessment was not completed and no data is present for the symptoms listed on the e CRF. Please review/update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:24:26
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:49:56
Query 'Per CDM: Assessment Not Done is checked however, there is data present on this form? Assessment Not Done should only be selected if the entire assessment was not completed and no data is present for the symptoms listed on the e CRF. Please review/update accordingly. Thank you.' answered with 'updated' (Site from DM).	Diana Toney (b) (4) (b) (4)	22 Feb 2021 13:43:08

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:10
User opened query 'Per CDM: Assessment Not Done is checked however, there is data present on this form? Assessment Not Done should only be selected if the entire assessment was not completed and no data is present for the symptoms listed on the e CRF. Please review/update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 09:20:34
User closed query 'Per CDM: It appears that O2 Saturation was not collected for Day1. If not collected, please consider recording these as Not Done.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 09:20:34
Query 'Per CDM: It appears that O2 Saturation was not collected for Day1. If not collected, please consider recording these as Not Done.' answered with 'O2 saturation not collected on this day' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 13:12:42
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User opened query 'Per CDM: It appears that O2 Saturation was not collected for Day1. If not collected, please consider recording these as Not Done.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 17:48:00
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered empty; reason for change Data Entry Error	douglas winter (b) (4)	23 Nov 2020 13:54:39
User entered '98'	douglas winter (b) (4)	17 Nov 2020 15:32:48

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	02 Mar 2021 17:04:41
User entered empty.	System	27 Feb 2021 18:49:05
User entered '%'	System	09 Feb 2021 13:12:03
User entered empty.	System	23 Nov 2020 13:54:39
User entered '%'	System	17 Nov 2020 15:32:48

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
User closed query 'Source appears to indicate that the subject's highest temp this day was 100.4F. Please confirm and revise if necessary.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:41:59
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:41:57
Query 'Source appears to indicate that the subject's highest temp this day was 100.4F. Please confirm and revise if necessary.' answered with 'ADDED TEMP' (Site from CRA).	douglas winter (b) (4) (b) (4)	03 Mar 2021 12:33:57
User entered '100.4' F reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Mar 2021 12:33:45
User opened query 'Source appears to indicate that the subject's highest temp this day was 100.4F. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 17:40:27
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 17:39:59
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:39:26
User entered missing code ND - Not Done; reason for change Data Entry Error	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
DataPoint Un-verified.	(b) (4), (b) (6)	27 Feb 2021 18:49:05
Signature has been broken.	(b) (4), (b) (6)	27 Feb 2021 18:49:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Feb 2021 18:49:05
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '100.4' F reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Nov 2020 13:54:39
User entered '36.7' C	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:32:48

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:39:26
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:07:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4)	17 Nov 2020 15:32:48
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:39:26
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:07:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	17 Nov 2020 15:32:48
	(b) (4)	

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:39:26
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:07:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	17 Nov 2020 15:32:48
	(b) (4)	

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:39:26
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:07:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	17 Nov 2020 15:32:48
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:39:26
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:07:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4)	17 Nov 2020 15:32:48
	(b) (4)	

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Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:39:26
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:07:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4)	17 Nov 2020 15:32:48
	(b) (4)	

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Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:39:26
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:07:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	17 Nov 2020 15:32:48
	(b) (4)	

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Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:39:26
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Severe (Severe)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:07:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Severe (Severe)'	douglas winter (b) (4)	17 Nov 2020 15:32:48
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:39:26
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:07:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4)	17 Nov 2020 15:32:48
	(b) (4)	

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Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:39:26
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:07:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4)	17 Nov 2020 15:32:48
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:39:26
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:07:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	17 Nov 2020 15:32:48
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:39:26
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:07:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4)	17 Nov 2020 15:32:48
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:39:26
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:07:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	17 Nov 2020 15:32:48
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:39:26
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:07:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	17 Nov 2020 15:32:48
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:39:26
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:07:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	17 Nov 2020 15:32:48
	(b) (4)	

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:39:26
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:07:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:42:45
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:10
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	17 Nov 2020 15:32:48
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 2 (Day 2)'	(b) (4) douglas winter (b) (4)	19 Nov 2020 14:53:57
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '14 Nov 2020' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 13:54:39
User entered '18 Nov 2020'	douglas winter (b) (4) (b) (4)	19 Nov 2020 14:53:57

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:49
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered '0' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '0'	douglas winter (b) (4) (b) (4)	19 Nov 2020 14:53:57

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:49
User entered missing code ND - Not Done; reason for change Data Entry Error	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
DataPoint Un-verified.	(b) (4), (b) (6)	27 Feb 2021 18:49:28
Signature has been broken.	(b) (4), (b) (6)	27 Feb 2021 18:49:28
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Feb 2021 18:49:28
User closed query 'Per CDM: Assessment Not Done is checked however, Assessment Not Done should only be selected if the entire assessment was empty. Please review/update accordingly, Else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 12:08:57
Query 'Per CDM: Assessment Not Done is checked however, Assessment Not Done should only be selected if the entire assessment was empty. Please review/update accordingly, Else clarify. Thank you.' answered with 'Assessment was not done so it is marked as not done' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	25 Feb 2021 14:25:32
User opened query 'Per CDM: Assessment Not Done is checked however, Assessment Not Done should only be selected if the entire assessment was empty. Please review/update accordingly, Else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:06:47
User closed query 'Per CDM: Assessment Not Done is checked however, there is data present on this form for O2 Saturation and Temperature? Assessment Not Done should only be selected if the entire assessment was not completed. Please review/update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:06:47

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Query 'Per CDM: Assessment Not Done is checked however, there is data present on this form for O2 Saturation and Temperature? Assessment Not Done should only be selected if the entire assessment was not completed. Please review/update accordingly. Thank you.' answered with 'subject did not complete this entry' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	24 Feb 2021 19:34:18
User opened query 'Per CDM: Assessment Not Done is checked however, there is data present on this form for O2 Saturation and Temperature? Assessment Not Done should only be selected if the entire assessment was not completed. Please review/update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:23:32
User closed query 'Per CDM: Assessment Not Done is checked however, there is data present on this form? Assessment Not Done should only be selected if the entire assessment was not completed and no data is present for the symptoms listed on the e CRF. Please review/update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:23:32
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:49:56
Query 'Per CDM: Assessment Not Done is checked however, there is data present on this form? Assessment Not Done should only be selected if the entire assessment was not completed and no data is present for the symptoms listed on the e CRF. Please review/update accordingly. Thank you.' answered with 'updated' (Site from DM).	Diana Toney (b) (4) (b) (4)	22 Feb 2021 13:45:02
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:13
User opened query 'Per CDM: Assessment Not Done is checked however, there is data present on this form? Assessment Not Done should only be selected if the entire assessment was not completed and no data is present for the symptoms listed on the e CRF. Please review/update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 09:21:27

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: It appears that both O2 Saturation and temperature were not collected for Days 2,3 and 4. If not collected, please consider recording these as Not Done. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 09:21:27
Query 'Per CDM: It appears that both O2 Saturation and temperature were not collected for Days 2,3 and 4. If not collected, please consider recording these as Not Done.	(b) (4), (b) (6)	09 Feb 2021 13:13:05
' answered with 'O2 saturation not collected on this day.' (Site from DM).		
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User opened query 'Per CDM: It appears that both O2 Saturation and temperature were not collected for Days 2,3 and 4. If not collected, please consider recording these as Not Done.	(b) (4), (b) (6)	08 Jan 2021 18:01:29
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered empty; reason for change Data Entry Error	douglas winter (b) (4)	23 Nov 2020 13:54:39
User entered '96'	douglas winter (b) (4)	19 Nov 2020 14:53:57

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	02 Mar 2021 17:04:41
User entered empty.	System	27 Feb 2021 18:49:28
User entered '%'	System	09 Feb 2021 13:12:03
User entered empty.	System	23 Nov 2020 13:54:39
User entered '%'	System	19 Nov 2020 14:53:57

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:42:56
DataPoint Un-verified.	douglas winter (b) (4)	03 Mar 2021 12:35:30
User entered '100.4' F reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	03 Mar 2021 12:35:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:49
User entered missing code ND - Not Done; reason for change Data Entry Error	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
DataPoint Un-verified.	(b) (4), (b) (6)	27 Feb 2021 18:49:28
Signature has been broken.	(b) (4), (b) (6)	27 Feb 2021 18:49:28
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Feb 2021 18:49:28
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered empty; reason for change Data Entry Error	douglas winter (b) (4) (b) (4)	23 Nov 2020 13:54:39
User entered '98.5' F	douglas winter (b) (4) (b) (4)	19 Nov 2020 14:53:57

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:49
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:08:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 13:54:39
User entered 'None (None)'	(b) (4) douglas winter (b) (4)	19 Nov 2020 14:53:57
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:49
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	19 Nov 2020 14:53:57
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:49
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	19 Nov 2020 14:53:57
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:49
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	19 Nov 2020 14:53:57
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:49
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:08:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 13:54:39
User entered 'None (None)'	(b) (4) douglas winter (b) (4)	19 Nov 2020 14:53:57
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:42:28
User closed query 'Source appears to indicate that muscle aches were moderate starting 13Nov2020 and continuing at the same severity until 17Nov2020. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:42:20
Query 'Source appears to indicate that muscle aches were moderate starting 13Nov2020 and continuing at the same severity until 17Nov2020. Please confirm and revise if necessary.' answered with 'CORRECTED' (Site from CRA).	douglas winter (b) (4) (b) (4)	03 Mar 2021 12:34:54
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Mar 2021 12:34:46
User opened query 'Source appears to indicate that muscle aches were moderate starting 13Nov2020 and continuing at the same severity until 17Nov2020. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 17:42:59
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 17:41:04
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:40:49
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
User entered 'Severe (Severe)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:02
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	Diana Toney (b) (4) (b) (4)	22 Feb 2021 13:44:55
User entered empty; reason for change Data Entry Error	Diana Toney (b) (4) (b) (4)	22 Feb 2021 13:44:55
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:13

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 13:54:39
User entered 'None (None)'	(b) (4)	
	douglas winter (b) (4)	19 Nov 2020 14:53:57
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:42:26
User closed query 'Body aches not recorded on source. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:42:24
Query 'Body aches not recorded on source. Please confirm and revise if necessary.' answered with 'CORRECTED TO NONE' (Site from CRA).	douglas winter (b) (4) (b) (4)	03 Mar 2021 12:35:02
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Mar 2021 12:34:46
User opened query 'Body aches not recorded on source. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 17:44:11
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 17:41:05
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:40:49
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
User entered 'Severe (Severe)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:02
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	Diana Toney (b) (4) (b) (4)	22 Feb 2021 13:44:55
User entered empty; reason for change Data Entry Error	Diana Toney (b) (4) (b) (4)	22 Feb 2021 13:44:55
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 13:54:39
User entered 'Mild (Mild)'	douglas winter (b) (4)	19 Nov 2020 14:53:57

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:49
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Severe (Severe)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Severe (Severe)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Nov 2020 13:54:39
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	19 Nov 2020 14:53:57

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:49
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:08:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4)	19 Nov 2020 14:53:57
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:49
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:08:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4)	19 Nov 2020 14:53:57
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:49
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	19 Nov 2020 14:53:57
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:49
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:08:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 13:54:39
User entered 'Mild (Mild)'	(b) (4) douglas winter (b) (4)	19 Nov 2020 14:53:57
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:49
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	19 Nov 2020 14:53:57
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:49
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	19 Nov 2020 14:53:57
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:49
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	19 Nov 2020 14:53:57
	(b) (4)	

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Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:49
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:44:55
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:13
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	19 Nov 2020 14:53:57
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 3 (Day 3)'	(b) (4) douglas winter (b) (4)	20 Nov 2020 14:33:22
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '15 Nov 2020' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 13:54:39
User entered '19 Nov 2020'	douglas winter (b) (4) (b) (4)	20 Nov 2020 14:33:22

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:51
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered '0' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User closed query 'Per CDM: Assessment Not Done is checked however, Assessment Not Done should only be selected if the entire assessment was empty. Please review/update accordingly, Else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 12:09:07
Query 'Per CDM: Assessment Not Done is checked however, Assessment Not Done should only be selected if the entire assessment was empty. Please review/update accordingly, Else clarify. Thank you.' answered with 'Assessment was not done so it is marked as not done' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	25 Feb 2021 14:25:39
User opened query 'Per CDM: Assessment Not Done is checked however, Assessment Not Done should only be selected if the entire assessment was empty. Please review/update accordingly, Else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:06:57
User closed query 'Per CDM: Assessment Not Done is checked however, there is data present on this form for O2 Saturation and Temperature? Assessment Not Done should only be selected if the entire assessment was not completed. Please review/update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:06:57
Query 'Per CDM: Assessment Not Done is checked however, there is data present on this form for O2 Saturation and Temperature? Assessment Not Done should only be selected if the entire assessment was not completed. Please review/update accordingly. Thank you.' answered with 'subject did not complete this entry' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	24 Feb 2021 19:35:09

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Assessment Not Done is checked however, there is data present on this form for O2 Saturation and Temperature? Assessment Not Done should only be selected if the entire assessment was not completed. Please review/update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:23:53
User closed query 'Per CDM: Assessment Not Done is checked however, there is data present on this form? Assessment Not Done should only be selected if the entire assessment was not completed and no data is present for the symptoms listed on the e CRF. Please review/update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:23:53
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
Query 'Per CDM: Assessment Not Done is checked however, there is data present on this form? Assessment Not Done should only be selected if the entire assessment was not completed and no data is present for the symptoms listed on the e CRF. Please review/update accordingly. Thank you.' answered with 'updated' (Site from DM).	Diana Toney (b) (4)	22 Feb 2021 13:46:02
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:17
User opened query 'Per CDM: Assessment Not Done is checked however, there is data present on this form? Assessment Not Done should only be selected if the entire assessment was not completed and no data is present for the symptoms listed on the e CRF. Please review/update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 09:21:46
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '0'	douglas winter (b) (4)	20 Nov 2020 14:33:22

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:51
User entered missing code ND - Not Done; reason for change Data Entry Error	douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Un-verified.	(b) (4)	27 Feb 2021 18:49:42
Signature has been broken.	(b) (4), (b) (6)	27 Feb 2021 18:49:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Feb 2021 18:49:42
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered empty; reason for change Data Entry Error	douglas winter (b) (4)	23 Nov 2020 13:54:39
User entered '96'	(b) (4) douglas winter (b) (4) (b) (4)	20 Nov 2020 14:33:22

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	02 Mar 2021 17:04:41
User entered empty.	System	27 Feb 2021 18:49:42
User entered '%'	System	09 Feb 2021 13:12:03
User entered empty.	System	23 Nov 2020 13:54:39
User entered '%'	System	20 Nov 2020 14:33:22

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:43:24
DataPoint Un-verified.	douglas winter (b) (4)	03 Mar 2021 12:36:12
User entered '100.4' F reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	03 Mar 2021 12:36:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:51
User entered missing code ND - Not Done; reason for change Data Entry Error	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
DataPoint Un-verified.	(b) (4), (b) (6)	27 Feb 2021 18:49:42
Signature has been broken.	(b) (4), (b) (6)	27 Feb 2021 18:49:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Feb 2021 18:49:42
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered empty; reason for change Data Entry Error	douglas winter (b) (4) (b) (4)	23 Nov 2020 13:54:39
User entered '98.6' F	douglas winter (b) (4) (b) (4)	20 Nov 2020 14:33:22

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:51
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 13:54:39
User entered 'None (None)'	(b) (4) douglas winter (b) (4)	20 Nov 2020 14:33:22
	(b) (4)	

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:51
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	20 Nov 2020 14:33:22
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:51
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	20 Nov 2020 14:33:22
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:51
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	20 Nov 2020 14:33:22
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:51
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:08:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4)	20 Nov 2020 14:33:22
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:43:32
User closed query 'Source appears to indicate that muscle aches were moderate starting 13Nov2020 and continuing at the same severity until 17Nov2020. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:43:29
Query 'Source appears to indicate that muscle aches were moderate starting 13Nov2020 and continuing at the same severity until 17Nov2020. Please confirm and revise if necessary.' answered with 'CORRECTED' (Site from CRA).	douglas winter (b) (4) (b) (4)	03 Mar 2021 12:36:21
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Mar 2021 12:36:12
User opened query 'Source appears to indicate that muscle aches were moderate starting 13Nov2020 and continuing at the same severity until 17Nov2020. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 17:44:43
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 17:44:33
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:40:51
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
User entered 'Severe (Severe)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:04
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	Diana Toney (b) (4) (b) (4)	22 Feb 2021 13:45:49
User entered empty; reason for change Data Entry Error	Diana Toney (b) (4) (b) (4)	22 Feb 2021 13:45:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:17

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4)	20 Nov 2020 14:33:22
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:43:37
User closed query 'Body aches not recorded on source. Please confirm and revise if necessary. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:43:35
Query 'Body aches not recorded on source. Please confirm and revise if necessary. ' answered with 'CORRECTED' (Site from CRA).	douglas winter (b) (4) (b) (4)	03 Mar 2021 12:36:27
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Mar 2021 12:36:12
User opened query 'Body aches not recorded on source. Please confirm and revise if necessary. ' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 17:44:51
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 17:44:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:40:51
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
User entered 'Severe (Severe)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:04
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	Diana Toney (b) (4) (b) (4)	22 Feb 2021 13:45:49
User entered empty; reason for change Data Entry Error	Diana Toney (b) (4) (b) (4)	22 Feb 2021 13:45:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	20 Nov 2020 14:33:22

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:51
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Severe (Severe)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Severe (Severe)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Nov 2020 13:58:19
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	20 Nov 2020 14:33:22

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:51
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4)	20 Nov 2020 14:33:22
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:51
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:08:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4)	20 Nov 2020 14:33:22
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:51
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	20 Nov 2020 14:33:22
	(b) (4)	

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:51
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:08:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 13:54:39
User entered 'None (None)'	(b) (4) douglas winter (b) (4)	20 Nov 2020 14:33:22
	(b) (4)	

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Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:51
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	20 Nov 2020 14:33:22
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:51
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	20 Nov 2020 14:33:22
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:51
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	20 Nov 2020 14:33:22
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:51
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:04
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:45:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	20 Nov 2020 14:33:22
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 4 (Day 4)'	(b) (4) douglas winter (b) (4)	23 Nov 2020 13:58:19
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '16 Nov 2020'	douglas winter (b) (4) (b) (4)	23 Nov 2020 13:58:19

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:54
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered '0' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User closed query 'Per CDM: Assessment Not Done is checked however, Assessment Not Done should only be selected if the entire assessment was empty. Please review/update accordingly, Else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 12:09:12
Query 'Per CDM: Assessment Not Done is checked however, Assessment Not Done should only be selected if the entire assessment was empty. Please review/update accordingly, Else clarify. Thank you.' answered with 'Assessment was not done so it is marked as not done' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	25 Feb 2021 14:26:10
User opened query 'Per CDM: Assessment Not Done is checked however, Assessment Not Done should only be selected if the entire assessment was empty. Please review/update accordingly, Else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:07:07
User closed query 'Per CDM: Assessment Not Done is checked however, there is data present on this form for O2 Saturation and Temperature? Assessment Not Done should only be selected if the entire assessment was not completed. Please review/update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:07:07
Query 'Per CDM: Assessment Not Done is checked however, there is data present on this form for O2 Saturation and Temperature? Assessment Not Done should only be selected if the entire assessment was not completed. Please review/update accordingly. Thank you.' answered with 'subject did not complete this entry' (Site from DM).	Crystal Paccione (b) (4) (b) (4)	24 Feb 2021 19:37:57

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Assessment Not Done is checked however, there is data present on this form for O2 Saturation and Temperature? Assessment Not Done should only be selected if the entire assessment was not completed. Please review/update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:24:01
User closed query 'Per CDM: Assessment Not Done is checked however, there is data present on this form? Assessment Not Done should only be selected if the entire assessment was not completed and no data is present for the symptoms listed on the e CRF. Please review/update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 09:24:01
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
Query 'Per CDM: Assessment Not Done is checked however, there is data present on this form? Assessment Not Done should only be selected if the entire assessment was not completed and no data is present for the symptoms listed on the e CRF. Please review/update accordingly. Thank you.' answered with 'updated' (Site from DM).	Diana Toney (b) (4)	22 Feb 2021 13:46:59
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:20
User opened query 'Per CDM: Assessment Not Done is checked however, there is data present on this form? Assessment Not Done should only be selected if the entire assessment was not completed and no data is present for the symptoms listed on the e CRF. Please review/update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 09:22:00
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '0'	douglas winter (b) (4)	23 Nov 2020 13:58:19

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:54
User entered missing code ND - Not Done; reason for change Data Entry Error	douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Un-verified.	(b) (4)	27 Feb 2021 18:50:02
Signature has been broken.	(b) (4), (b) (6)	27 Feb 2021 18:50:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Feb 2021 18:50:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered empty; reason for change Data Entry Error	douglas winter (b) (4)	23 Nov 2020 14:01:51
User entered '98'	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 13:58:19

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	02 Mar 2021 17:04:41
User entered empty.	System	27 Feb 2021 18:50:02
User entered '%'	System	09 Feb 2021 13:12:03
User entered empty.	System	23 Nov 2020 14:01:51
User entered '%'	System	23 Nov 2020 13:58:19

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:43:45
DataPoint Un-verified.	douglas winter (b) (4)	03 Mar 2021 12:36:59
User entered '100.4' F reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	03 Mar 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:54
User entered missing code ND - Not Done; reason for change Data Entry Error	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
DataPoint Un-verified.	(b) (4), (b) (6)	27 Feb 2021 18:50:02
Signature has been broken.	(b) (4), (b) (6)	27 Feb 2021 18:50:02
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Feb 2021 18:50:02
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered empty; reason for change Data Entry Error	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51
User entered '36.7' C	douglas winter (b) (4) (b) (4)	23 Nov 2020 13:58:19

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:54
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:08:07
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4)	23 Nov 2020 13:58:19
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:54
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:07
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	23 Nov 2020 13:58:19
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:54
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:07
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	23 Nov 2020 13:58:19
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:54
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:07
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	23 Nov 2020 13:58:19
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:54
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:08:07
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4)	23 Nov 2020 13:58:19
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:43:51
User closed query 'Source appears to indicate that muscle aches were moderate starting 13Nov2020 and continuing at the same severity until 17Nov2020. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:43:48
Query 'Source appears to indicate that muscle aches were moderate starting 13Nov2020 and continuing at the same severity until 17Nov2020. Please confirm and revise if necessary.' answered with 'CORRECTED' (Site from CRA).	douglas winter (b) (4) (b) (4)	03 Mar 2021 12:37:07
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Mar 2021 12:36:59
User opened query 'Source appears to indicate that muscle aches were moderate starting 13Nov2020 and continuing at the same severity until 17Nov2020. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 17:45:16
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 17:44:57
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:40:54
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
User entered 'Severe (Severe)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:07
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	Diana Toney (b) (4) (b) (4)	22 Feb 2021 13:46:49
User entered empty; reason for change Data Entry Error	Diana Toney (b) (4) (b) (4)	22 Feb 2021 13:46:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:20

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4)	23 Nov 2020 13:58:19
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:43:55
User closed query 'Body aches not recorded on source. Please confirm and revise if necessary. ' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 16:43:53
Query 'Body aches not recorded on source. Please confirm and revise if necessary. ' answered with 'CORRECTED TO NONE' (Site from CRA).	douglas winter (b) (4) (b) (4)	03 Mar 2021 12:37:13
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	03 Mar 2021 12:36:59
User opened query 'Body aches not recorded on source. Please confirm and revise if necessary. ' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 17:45:23
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 17:44:59
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:40:54
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
User entered 'Severe (Severe)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:07
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	Diana Toney (b) (4) (b) (4)	22 Feb 2021 13:46:49
User entered empty; reason for change Data Entry Error	Diana Toney (b) (4) (b) (4)	22 Feb 2021 13:46:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 13:58:19

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:54
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Severe (Severe)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:07
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Severe (Severe)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 13:58:19

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:54
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:08:07
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4)	23 Nov 2020 13:58:19
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:54
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:08:07
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4)	23 Nov 2020 13:58:19
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:54
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:07
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	23 Nov 2020 13:58:19
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:54
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:08:07
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4)	23 Nov 2020 13:58:19
	(b) (4)	

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Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:54
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:07
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	23 Nov 2020 13:58:19
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:54
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:07
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	23 Nov 2020 13:58:19
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:54
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:07
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	23 Nov 2020 13:58:19
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:08:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 17:40:54
DataPoint Un-verified.	douglas winter (b) (4)	02 Mar 2021 17:04:41
Signature has been broken.	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	02 Mar 2021 17:04:41
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:07
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Un-verified.	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
User entered empty; reason for change Data Entry Error	(b) (4) Diana Toney (b) (4)	22 Feb 2021 13:46:49
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:24:20
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 13:12:03
User entered 'Not Done (Not Done)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:12:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4)	23 Nov 2020 13:58:19
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 5 (Day 5)'	(b) (4) douglas winter (b) (4)	23 Nov 2020 14:01:51
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '17 Nov 2020'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '0'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '98'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	23 Nov 2020 14:01:51

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '36.7' C	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:01:51

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 6 (Day 6)'	(b) (4) douglas winter (b) (4)	23 Nov 2020 14:03:49
	(b) (4)	

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '18 Nov 2020'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '0'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '96'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Nov 2020 14:07:34
User entered '98.5' F reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Nov 2020 14:03:49
User entered '98.5' (non-conformant).	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:03:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 7 (Day 7)'	(b) (4) douglas winter (b) (4)	23 Nov 2020 14:07:34
	(b) (4)	

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '19 Nov 2020'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '0'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '96'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '98.6' F	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:07:34

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 8 (Day 8)'	(b) (4) douglas winter (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '20 Nov 2020'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '0'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '94'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '98.3' F	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 9 (Day 9)' reason for change:	(b) (4)	
Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4)	
	douglas winter (b) (4)	23 Nov 2020 14:52:35
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 15:01:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 15:01:55
User entered '21 Nov 2020' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Nov 2020 15:01:55
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 14:52:35
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '0'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '95' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	23 Nov 2020 15:01:55
User entered empty.	System	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '98.3' F reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Mild (Mild)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Nov 2020 15:01:55
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Nov 2020 15:01:55
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Nov 2020 15:01:55
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 10 (Day 10)' reason for change:	(b) (4)	
Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4)	
	douglas winter (b) (4)	23 Nov 2020 14:52:35
	(b) (4)	

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 15:01:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 15:01:55
User entered '22 Nov 2020' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Nov 2020 15:01:55
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 14:52:35
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

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Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '0'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '97' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	23 Nov 2020 15:01:55
User entered empty.	System	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered '98.3' F reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:26:34
User closed query 'Progress note from this date indicates this is severe. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 19:26:33
Query 'Progress note from this date indicates this is severe. Please confirm and revise if necessary.' answered with 'Revised' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 13:14:27
User entered 'Severe (Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:14:14
User opened query 'Progress note from this date indicates this is severe. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 17:04:07
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:57:12
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:57:12
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Severe (Severe)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Nov 2020 15:01:55
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'Mild (Mild)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:45:40
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	23 Nov 2020 15:01:55
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	23 Nov 2020 14:52:35

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 11 (Day 11)'	(b) (4) douglas winter (b) (4)	30 Nov 2020 19:46:32
	(b) (4)	

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:05:11
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 19:52:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Nov 2020 19:52:13
User entered '23 Nov 2020' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:52:13
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 19:46:32
User entered empty.	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:05:13
User entered '0'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:05:15
User entered '96' reason for change: Data Entry Error	douglas winter (b) (4)	30 Nov 2020 19:52:13
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	30 Nov 2020 19:52:13
User entered empty.	System	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:05:17
User entered '97.0' F reason for change: Data Entry Error	douglas winter (b) (4)	30 Nov 2020 19:52:13
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:05:19
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	30 Nov 2020 19:52:13
User entered empty.	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:05:21
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	30 Nov 2020 19:52:13
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:05:03
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4)	30 Nov 2020 19:52:13
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:05:22
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	30 Nov 2020 19:52:13
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:05:24
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	30 Nov 2020 19:52:13
User entered empty.	douglas winter (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:05:26
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	30 Nov 2020 19:52:13
User entered empty.	douglas winter (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:05:28
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	30 Nov 2020 19:52:13
User entered empty.	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:04:52
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4)	30 Nov 2020 19:52:13
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:04:46
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4)	30 Nov 2020 19:52:13
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:04:48
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4)	30 Nov 2020 19:52:13
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:04:55
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	douglas winter (b) (4)	30 Nov 2020 19:52:13
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:05:30
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	30 Nov 2020 19:52:13
User entered empty.	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:05:32
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	30 Nov 2020 19:52:13
User entered empty.	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:05:34
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	30 Nov 2020 19:52:13
User entered empty.	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:05:35
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	30 Nov 2020 19:52:13
User entered empty.	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:05:37
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	30 Nov 2020 19:52:13
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	30 Nov 2020 19:46:32

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 12 (Day 12)'	(b) (4) douglas winter (b) (4)	30 Nov 2020 19:59:31
	(b) (4)	

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:08:12
User entered '24 Nov 2020'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:08:09
User entered '0'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:08:07
User entered '95'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:08:06
User entered '97.6' F	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:08:04
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:08:03
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:28:31
User closed query 'Source from this date indicates this is Mod. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 19:28:29
Query 'Source from this date indicates this is Mod. Please confirm and revise if necessary.' answered with 'Revised' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 13:15:28
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:15:22
User opened query 'Source from this date indicates this is Mod. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 17:07:36
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:41
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 17:06:32
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:08:00
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:06:14
User entered 'Severe (Severe)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:06:19
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:07:58
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:07:56
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:08:27
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:08:32
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:06:23
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:06:26
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:07:51
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:07:49
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:07:19
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:07:45
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 19:59:31

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 13 (Day 13)'	(b) (4) douglas winter (b) (4)	30 Nov 2020 20:01:49
	(b) (4)	

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:09:31
User entered '25 Nov 2020'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:09:33
User entered '0'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:09:35
User entered '95'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:09:37
User entered '98.0' F	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:09:58
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:11:13
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:10:52
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:11:11
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:10:28
User entered 'Severe (Severe)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:10:36
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:11:08
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:10:16
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:10:09
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:10:11
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:10:44
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:10:48
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:10:59
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:11:01
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:11:03
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:11:05
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:01:49

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 14 (Day 14)'	(b) (4) douglas winter (b) (4)	30 Nov 2020 20:04:07
	(b) (4)	

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:12:47
User entered '26 Nov 2020'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:12:58
User entered '0'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:13:03
User entered '96'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:13:05
User entered '98.1' F	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:13:07
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:13:09
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:13:10
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:13:12
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:12:37
User entered 'Severe (Severe)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:13:14
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:13:15
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:12:02
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:11:41
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:11:43
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:12:27
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:13:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:13:19
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:13:21
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:13:26
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:13:29
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:04:07

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 15 (Day 15)'	(b) (4) douglas winter (b) (4)	30 Nov 2020 20:07:18
	(b) (4)	

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:13:58
User entered '27 Nov 2020'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:01
User entered '0'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:02
User entered '96'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:04
User entered '98.6' F	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:29
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:15
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:26
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:31
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:32
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:34
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:35
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:18
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:11
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:10
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:39
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:41
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:43
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:46
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:21
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:14:48
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:07:18

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 16 (Day 16)'	(b) (4) douglas winter (b) (4)	30 Nov 2020 20:10:20
	(b) (4)	

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:15:12
User entered '28 Nov 2020'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:15:14
User entered '0'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:15:16
User entered '95'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:15:18
User entered '98.0' F	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:16:40
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:15:35
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:17:09
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:17:15
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:15:32
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:17:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:17:20
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:17:02
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:15:25
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:15:23
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:17:22
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:17:24
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:17:27
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:17:30
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:17:34
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:17:36
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:10:20

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 17 (Day 17)'	(b) (4) douglas winter (b) (4)	30 Nov 2020 20:12:24
	(b) (4)	

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:18:05
User entered '29 Nov 2020'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:18:07
User entered '0'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:18:08
User entered '96'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:18:10
User entered '97.9' F	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:18:59
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:18:28
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:18:39
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:19:01
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:18:42
User entered 'Severe (Severe)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:19:03
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:19:05
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:18:33
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:18:21
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:18:23
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:19:10
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:19:12
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:19:14
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:19:16
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:18:53
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:19:19
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	30 Nov 2020 20:12:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 18 (Day 18)'	(b) (4) douglas winter (b) (4)	02 Dec 2020 14:07:00
	(b) (4)	

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:19:30
User entered '30 Nov 2020'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:19:32
User entered '0'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:19:35
User entered '94'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:29:35
User entered '98.1' F	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:29:37
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:29:04
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:29:15
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:29:19
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:29:10
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:29:42
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:29:43
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:28:56
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:28:58
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:29:02
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:29:33
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:29:31
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:29:29
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:29:27
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:29:26
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:29:24
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:07:00

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 19 (Day 19)'	(b) (4) douglas winter (b) (4)	02 Dec 2020 14:18:47
	(b) (4)	

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:07
User entered '01 Dec 2020'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:07
User entered '0'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:07
User entered '97'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:07
User entered '98.3' F	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:07
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:07
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:09:51
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:07
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:09:54
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:07
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:07
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:09:46
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:09:42
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:09:44
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:07
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:07
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:07
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:07
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:07
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:07
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	02 Dec 2020 14:18:47

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 20 (Day 20)'	(b) (4) douglas winter (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:11:24
User entered '2 Dec 2020'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:11:25
User entered '0'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:11:27
User entered '95'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:11:29
User entered '97.6' F	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:11:33
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:11:35
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:11:36
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:11:38
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:28:53
User closed query 'This is not indicated in the source for this day. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 19:28:51
Query 'This is not indicated in the source for this day. Please confirm and revise if necessary.' answered with 'Revised' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 13:16:37
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:16:31
User opened query 'This is not indicated in the source for this day. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:12:20
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:11:43
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:11:46
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:10:48
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:11:11
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:11:14
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:11:00
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:11:48
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:11:49
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:11:51
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:11:53
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:11:55
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:35:54

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 21 (Day 21)'	(b) (4) douglas winter (b) (4)	04 Dec 2020 21:37:56
	(b) (4)	

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:29
User entered '3 Dec 2020'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:29
User entered '0'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:29
User entered '95'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:29
User entered '98.1' F	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:29
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:05
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:58
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:29
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:12:54
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:29
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:29
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:00
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:15
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:17
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:29
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:29
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:29
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:29
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:29
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:29
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:37:56

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 22 (Day 22)'	(b) (4) douglas winter (b) (4)	09 Dec 2020 13:48:50
	(b) (4)	

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:56
User entered '4 Dec 2020'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:13:57
User entered '0'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:29:06
User closed query 'Source indicates this is 94. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 19:29:04
Query 'Source indicates this is 94. Please confirm and revise if necessary.' answered with 'Revised' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 13:17:56
User entered '94' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:17:49
User opened query 'Source indicates this is 94. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:16:01
User entered '95'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:14:03
User entered '98' F	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:15:35
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:14:18
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:15:33
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:15:31
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:15:07
User entered 'Severe (Severe)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:15:28
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:15:26
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:15:04
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:14:23
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:14:25
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:14:16
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:15:17
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:15:19
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:15:21
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:15:23
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:15:25
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:48:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 23 (Day 23)'	(b) (4) douglas winter (b) (4)	09 Dec 2020 13:50:50
	(b) (4)	

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:17:26
User entered '5 Dec 2020'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:17:28
User entered '0'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:17:35
User entered '95'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:17:39
User entered '99.3' F	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:17:42
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:17:47
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:16:44
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:17:49
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:29:20
User closed query 'Source indicates this is moderate for this day. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 19:29:18
Query 'Source indicates this is moderate for this day. Please confirm and revise if necessary.' answered with 'Revised' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 13:18:30
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:18:24
User opened query 'Source indicates this is moderate for this day. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:17:23
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:17:13
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:17:11
User entered 'Severe (Severe)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:17:52
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:17:54
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:16:41
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:17:55
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:17:57
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:08:19
User closed query 'Please confirm as this still states Moderate.' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 18:08:16
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
Query 'Please confirm as this still states Moderate.' answered with '05dec2020 for nasal congestion states mild' (Site from CRA).	(b) (4)	
	Diana Toney (b) (4)	22 Feb 2021 13:49:35
	(b) (4)	
User entered 'Mild (Mild)' reason for change: Data Entry Error	Diana Toney (b) (4)	22 Feb 2021 13:49:08
	(b) (4)	
User opened query 'Please confirm as this still states Moderate.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 19:29:55
User closed query 'Source indicates this is mild for this day. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 19:29:55
Query 'Source indicates this is mild for this day. Please confirm and revise if necessary.' answered with 'Revised' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 13:18:45
User opened query 'Source indicates this is mild for this day. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:17:05
User entered 'Moderate (Moderate)'	douglas winter (b) (4)	09 Dec 2020 13:50:50
	(b) (4)	

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:18:00
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:18:02
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:18:03
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:29:31
User closed query 'Source indicates this is mild for this day. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 19:29:28
Query 'Source indicates this is mild for this day. Please confirm and revise if necessary.' answered with 'Revised' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 13:19:58
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:18:39
User opened query 'Source indicates this is mild for this day. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:16:34
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:18:08
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:50:50

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User closed query 'Subject has continuing symptoms and source appears to indicate that subject was contacted through at least 13Dec2020. Please enter those as additional log lines in the symptom log form.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:30:14
Query 'Subject has continuing symptoms and source appears to indicate that subject was contacted through at least 13Dec2020. Please enter those as additional log lines in the symptom log form.' answered with 'Logs through 13 Dec 2020 completed' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 13:38:56
User opened query 'Subject has continuing symptoms and source appears to indicate that subject was contacted through at least 13Dec2020. Please enter those as additional log lines in the symptom log form.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:34:33
User entered 'Day 24 (Day 24)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:19:01
User entered '6 Dec 2020'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:19:02
User entered '0'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:19:04
User entered '95'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:19:06
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Dec 2020 13:52:27
User entered '98.1' F reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:27
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Dec 2020 13:52:21
User entered '98.1' (non-conformant).	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:19:08
User entered 'None (None)' reason for change: Data Entry Error	douglas winter (b) (4)	09 Dec 2020 13:52:35
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:18:38
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:18:36
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:19:10
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:30:29
User closed query 'Source indicates this is moderate for this day. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 19:30:27
Query 'Source indicates this is moderate for this day. Please confirm and revise if necessary.' answered with 'Revised' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 13:19:35
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 13:19:27
User opened query 'Source indicates this is moderate for this day. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 18:18:57
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:19:12
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:19:15
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:18:32
User entered 'Moderate (Moderate)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:18:28
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:18:30
User entered 'Mild (Mild)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:19:23
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:19:27
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:19:29
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:19:31
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:19:35
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:19:38
User entered 'None (None)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 13:52:21

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 25 (Day 25)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:22
User entered '7 Dec 2020'	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:22
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:22
User entered '95'	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:22
User entered '98.7' F	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:22
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:22
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:22
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:22
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:16:15
User entered 'Severe (Severe)'	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:22
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:22
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:16:06
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:16:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:16:04
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:16:11
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:22
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:22
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:22
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:22
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:22
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:27:11

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 26 (Day 26)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:28
User entered '8 Dec 2020'	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:28
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:28
User entered '95'	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:28
User entered '99.7' F	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:16:49
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:16:56
User entered 'Severe (Severe)'	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:16:54
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:16:44
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:16:46
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:29:14

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 27 (Day 27)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:30
User entered '9 Dec 2020'	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:30
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:30
User entered '94'	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:30
User entered '99' F	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:17:34
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:17:36
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:17:30
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:17:32
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:30
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:30:59

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 28 (Day 28)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:34
User entered '10 Dec 2020'	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:34
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:34
User entered '94'	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:34
User entered '98.8' F	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:34
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:17:59
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:34
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:34
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:17:53
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:34
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:34
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:34
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:17:55
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:17:57
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:34
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:34
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:34
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:34
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:34
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:18:34
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:32:24

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 29 (Day 29)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:56
User entered '11 Dec 2020'	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:56
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:56
User entered '94'	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:56
User entered '97.9' F	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:56
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:56
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:09
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:56
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:11
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:56
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:56
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:56
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:56
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:56
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:56
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:56
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:56
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:56
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:56
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:56
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:34:44

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 30 (Day 30)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:59
User entered '12 Dec 2020'	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:59
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:59
User entered '92'	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:59
User entered '97.7' F	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:59
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:34
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:59
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:59
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:46
User entered 'Severe (Severe)'	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:59
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:59
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:36
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:41
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:43
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:59
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:59
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:59
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:59
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:59
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:21:59
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:36:30

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
User entered 'Day 31 (Day 31)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:28
User entered '13 Dec 2020'	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:28
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:28
User entered '95'	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User entered '%'	System	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:28
User entered '97.7' F	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:12
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:14
User entered 'Moderate (Moderate)'	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:17
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:18
User entered 'Mild (Mild)'	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Symptom Log (31)

Generated On: 09 Jun 2021 16:02:02

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:15
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:22:28
User entered 'None (None)'	(b) (4), (b) (6)	09 Feb 2021 13:38:05

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:23
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:08
User entered '17 Nov 2020'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:33:23

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:23
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:08
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:33:23

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:23
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:08
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 13:34:45
User closed query 'Please reconcile as central lab provided positive results to the site' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:18:10
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'CONFIRMED' (Site from System).	douglas winter (b) (4) (b) (4)	23 Nov 2020 13:38:56
Query 'Please reconcile as central lab provided positive results to the site' answered with 'UPDATED' (Site from CRA).	douglas winter (b) (4) (b) (4)	23 Nov 2020 13:38:41
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	23 Nov 2020 13:38:25
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Nov 2020 13:38:25
User opened query 'Please reconcile as central lab provided positive results to the site' (Site from CRA).	(b) (4), (b) (6)	21 Nov 2020 16:56:23
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 19:49:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 19:49:55
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	17 Nov 2020 19:49:55
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 15:33:23
User entered empty.	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:33:23

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:23
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:08
User entered '17 Nov 2020'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:33:23

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:23
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:08
User entered 'Nasal Swab (Nasal Swab)'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:33:23

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:23
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:08
User entered empty.	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:33:23

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:23
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:08
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:33:23

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:23
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:08
User entered empty.	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:33:23

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:23
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:08
User entered empty.	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:33:23

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:02:02

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:23
User entered '1'	System	23 Nov 2020 13:38:25
User entered '0'	System	17 Nov 2020 19:49:55

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:02:02

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:02:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:02:02

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:02:02

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:02:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

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Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:38:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User closed query 'Per CDM : Please note as per the Symptom log the O2 saturation is 92% on Day 30 (12DEC20), Kindly note "Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?"is NO. Kindly reconcile with the symptom log and make appropriate corrections or else clarify. Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 09:37:55
Query 'Per CDM : Please note as per the Symptom log the O2 saturation is 92% on Day 30 (12DEC20), Kindly note "Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?"is NO. Kindly reconcile with the symptom log and make appropriate corrections or else clarify. Thanks ' answered with 'CORRECTED SO CRF AND SOURCE MATCH' (Site from DM).	douglas winter (b) (4) (b) (4)	23 Apr 2021 11:33:11
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	23 Apr 2021 11:32:52
Signature has been broken.	douglas winter (b) (4) (b) (4)	23 Apr 2021 11:32:52
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Apr 2021 11:32:52
User opened query 'Per CDM : Please note as per the Symptom log the O2 saturation is 92% on Day 30 (12DEC20), Kindly note "Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?"is NO. Kindly reconcile with the symptom log and make appropriate corrections or else clarify. Thanks ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 11:29:21
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 14:38:29
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	26 Apr 2021 13:48:13
DataPoint Un-verified.	douglas winter (b) (4) (b) (4)	23 Apr 2021 11:32:52
Signature has been broken.	douglas winter (b) (4) (b) (4)	23 Apr 2021 11:32:52
User entered '12 Dec 2020' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Apr 2021 11:32:52
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:12:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:00:49
Signature has been broken.	(b) (4), (b) (6)	27 Apr 2021 14:50:46
User entered '13 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Apr 2021 14:50:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Un-verified.	(b) (4) douglas winter (b) (4)	23 Apr 2021 11:32:52
Signature has been broken.	(b) (4) douglas winter (b) (4)	23 Apr 2021 11:32:52
User entered '15 Dec 2020' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	23 Apr 2021 11:32:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	28 Apr 2021 22:12:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:00:52
Signature has been broken.	(b) (4), (b) (6)	27 Apr 2021 14:50:46
User entered '92' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Apr 2021 14:50:46
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Un-verified.	(b) (4) douglas winter (b) (4)	23 Apr 2021 11:32:52
Signature has been broken.	(b) (4) douglas winter (b) (4)	23 Apr 2021 11:32:52
User entered '96' reason for change: Data Entry Error	(b) (4) douglas winter (b) (4)	23 Apr 2021 11:32:52
User signature succeeded.	(b) (4) Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered empty.	(b) (4) douglas winter (b) (4)	23 Nov 2020 14:10:09

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

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Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

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User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

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User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

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Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
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[Evidence of Shock Requires Vasopressors](#)

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User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

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[Acute Renal Dysfunction?](#)

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Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
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[Neurologic Dysfunction?](#)

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Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:02:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:02:02

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:02:02

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:02:02

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:02:02

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:02:02

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:02:02

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 16:02:02

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:30
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:20
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:10:09

US3222117

Folder: Covid-19 Assessment 17 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:02:02

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:52:35
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:28
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Nov 2020 13:37:52
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:33:37

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:02:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User accepted default value 'Day 3 (Day 3)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:02:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:22:41
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:02:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:22:41
User entered '19 Nov 2020'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:02:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User accepted default value 'Day 5 (Day 5)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:02:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:22:46
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:02:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:22:46
User entered '21 Nov 2020'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:02:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User accepted default value 'Day 7 (Day 7)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:02:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:22:55
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:02:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:22:55
User entered '23 Nov 2020'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:02:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User accepted default value 'Day 9 (Day 9)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:02:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:14:36
User closed query 'Per CDM: Date of collection recorded as 25NOV2020 reflects that the sample has been collected however the response to Was sample collected? is recorded as NA (COVID-19 Negative). Please review and update the response as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 09:11:48
Query 'Per CDM: Date of collection recorded as 25NOV2020 reflects that the sample has been collected however the response to Was sample collected? is recorded as NA (COVID-19 Negative). Please review and update the response as appropriate. ' answered with 'Updated' (Site from DM).	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:56:08
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:55:58
User opened query 'Per CDM: Date of collection recorded as 25NOV2020 reflects that the sample has been collected however the response to Was sample collected? is recorded as NA (COVID-19 Negative). Please review and update the response as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 07:33:52
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 21:45:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 21:45:45
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:45:45
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 21:41:32
User entered empty.	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:02:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:14:36
User entered '25 Nov 2020' reason for change: Data Entry Error	douglas winter (b) (4)	04 Dec 2020 21:45:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:02:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User closed query 'Per GCL Reconciliation: Saliva sample collected on 17DEC2020 is labeled under "Unscheduled Visit COVID" in Viracor data and in GCL it is labeled under "Convisit D28". Please verify the correct visit for sample collected on this date. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 03:04:48
Query 'Per GCL Reconciliation: Saliva sample collected on 17DEC2020 is labeled under "Unscheduled Visit COVID" in Viracor data and in GCL it is labeled under "Convisit D28". Please verify the correct visit for sample collected on this date. ' answered with 'Unscheduled Visit visit 2 (Day 28)' (Site from DM).	douglas winter (b) (4) (b) (4)	16 Feb 2021 02:05:22
User opened query 'Per GCL Reconciliation: Saliva sample collected on 17DEC2020 is labeled under "Unscheduled Visit COVID" in Viracor data and in GCL it is labeled under "Convisit D28". Please verify the correct visit for sample collected on this date. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 17:09:46
Query 'Per GCL Reconciliation: Saliva sample collected on 17DEC2020 is labeled under "Unscheduled Visit COVID" in Viracor data and in GCL it is labelled under "Illness D3-D21". Please verify the correct visit for sample collected on this date. ' canceled (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 17:09:34
User opened query 'Per GCL Reconciliation: Saliva sample collected on 17DEC2020 is labeled under "Unscheduled Visit COVID" in Viracor data and in GCL it is labelled under "Illness D3-D21". Please verify the correct visit for sample collected on this date. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 16:46:53
Query 'Per GCL Lab Reconciliation: Saliva: Per GCL, there is a Saliva sample with a Collection Date of 17DEC2020, however this sample is missing in EDC. Please review if the sample has been collected and update the details in this Saliva collection log, as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 10:43:38

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:02:02

[Visit](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Per GCL, there is a Saliva sample with a Collection Date of 17DEC2020, however this sample is missing in EDC. Please review if the sample has been collected and update the details in this Saliva collection log, as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 18:10:50
User accepted default value 'Day 14 (Day 14)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:02:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:14:36
User closed query 'Per CDM: Date of collection recorded as 30NOV2020 reflects that the sample has been collected however the response to Was sample collected? is recorded as NA (COVID-19 Negative). Please review and update the response as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 09:11:57
Query 'Per CDM: Date of collection recorded as 30NOV2020 reflects that the sample has been collected however the response to Was sample collected? is recorded as NA (COVID-19 Negative). Please review and update the response as appropriate. ' answered with 'Updated' (Site from DM).	douglas winter (b) (4) (b) (4)	16 Feb 2021 02:05:39
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:56:24
User opened query 'Per CDM: Date of collection recorded as 30NOV2020 reflects that the sample has been collected however the response to Was sample collected? is recorded as NA (COVID-19 Negative). Please review and update the response as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 07:34:43
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 21:45:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 21:45:45
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:45:45
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 21:41:32
User entered empty.	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:02:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:14:36
User entered '30 Nov 2020' reason for change: Data Entry Error	douglas winter (b) (4)	04 Dec 2020 21:45:45
User entered empty.	(b) (4) douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:02:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User accepted default value 'Day 21 (Day 21)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:02:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:14:36
User closed query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 07DEC2020 labelled as Illness Visit which is missing in EDC. Please confirm if the sample has been collected then record on the Saliva collection form. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 10:22:39
Query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 07DEC2020 labelled as Illness Visit which is missing in EDC. Please confirm if the sample has been collected then record on the Saliva collection form. Thank you.' answered with 'updated' (Site from DM).	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:54:54
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:54:46
Query 'Data is required. Please complete.' canceled (Site from System).	(b) (4), (b) (6)	08 Jan 2021 10:44:24
User opened query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 07DEC2020 labelled as Illness Visit which is missing in EDC. Please confirm if the sample has been collected then record on the Saliva collection form. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 10:44:21
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 21:41:32
User entered empty.	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:02:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:20:14
User closed query 'Per GCL LAB reconciliation: Saliva Re-query : PPD reports Day 21 sample with Accession # 1F600042154 is reported with 07DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Please note DAY 21 date is prior to the Day 14 date. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 10:59:06
Query 'Per GCL LAB reconciliation: Saliva Re-query Jennifer Dittman : PPD reports Day 21 sample with Accession # 1F600042154 is reported with 07DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Please note DAY 21 date is prior to the Day 14 date. ' answered with 'updated' (Site from DM).	Jennifer Dittman (b) (4) (b) (4)	05 Apr 2021 20:21:26
DataPoint Un-verified.	Jennifer Dittman (b) (4) (b) (4)	05 Apr 2021 20:21:05
Signature has been broken.	Jennifer Dittman (b) (4) (b) (4)	05 Apr 2021 20:21:05
User entered '07 Dec 2020' reason for change: Data Entry Error	Jennifer Dittman (b) (4) (b) (4)	05 Apr 2021 20:21:05
User opened query 'Per GCL LAB reconciliation: Saliva Re-query : PPD reports Day 21 sample with Accession # 1F600042154 is reported with 07DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Please note DAY 21 date is prior to the Day 14 date. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:47:54
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:14:36

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:02:02

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F600042154 is reported with 07DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:12:48
Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F600042154 is reported with 07DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with 'CORRECTED DATE' (Site from DM).	douglas winter (b) (4) (b) (4)	19 Feb 2021 03:12:27
User entered '21 Nov 2020' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	19 Feb 2021 03:12:09
User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 21 sample with Accession # 1F600042154 is reported with 07DEC2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 10:22:36
User entered '19 Nov 2020' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:54:46
User entered empty.	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:02:02

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17DEC2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 11:12:39
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17DEC2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit.' answered with 'THE SUBJECT WAS HOSPITALIZED (SAE) AND 17/DEC/2020 WAS HIS DAY 28.' (Site from DM).	douglas winter (b) (4) (b) (4)	19 Feb 2021 03:16:01
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17DEC2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:24:27
User accepted default value 'Day 28 (Day 28)'	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:02:02

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:14:36
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4)	19 Feb 2021 03:10:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Feb 2021 03:09:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 03:09:29
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	douglas winter (b) (4)	19 Feb 2021 03:09:29
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Dec 2020 21:41:32
User entered empty.	System	04 Dec 2020 21:41:32
	douglas winter (b) (4)	04 Dec 2020 21:41:32
	(b) (4)	

US3222117

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:02:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:27
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:14:36
User entered '17 Dec 2020' reason for change: Data Entry Error	douglas winter (b) (4)	19 Feb 2021 03:10:24
User entered empty.	douglas winter (b) (4) (b) (4)	04 Dec 2020 21:41:32

US3222117

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21NOV2020, 23NOV2020 and 25NOV2020 are reported under Illness visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 10:43:02
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19NOV2020 is reported under Illness visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 10:42:59
Comment added 'SUBJECT IS STILL UNDER OBSERVATION AND AE HAS NOT YET ENDED.'	Albert Garcia (b) (4)	09 Dec 2020 19:56:33
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 21NOV2020, 23NOV2020 and 25NOV2020 are reported under Illness visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 05:14:02
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19NOV2020 is reported under Illness visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 01:58:36
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:46:58

US3222117

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Please reconcile and enter saliva log' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 20:46:55
Query 'Please reconcile and enter saliva log' answered with 'I will' (Site from CRA).	douglas winter (b) (4)	24 Nov 2020 14:00:05
User opened query 'Please reconcile and enter saliva log' (Site from CRA).	(b) (4)	21 Nov 2020 16:56:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Nov 2020 16:56:50
	douglas winter (b) (4)	17 Nov 2020 15:26:07
	(b) (4)	

US3222117

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 17 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 07:12:59
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 17 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you' answered with 'Convalescence Visit Day 28' (Site from DM).	douglas winter (b) (4) (b) (4)	16 Feb 2021 02:06:42
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 17 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 08:30:11
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 17 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. Please review if the sample SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 08:29:35

US3222117

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: SARS-CoV-2 serum sample dated 17 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample is missing in EDC. Please review if the sample SARS-CoV-2 serum sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 08:10:20
User entered '17 Nov 2020'	douglas winter (b) (4)	17 Nov 2020 15:26:07
	(b) (4), (b) (6)	24 Nov 2020 20:46:58

US3222117

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:46:58
User entered 'Clinic (Clinic)'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:26:07

US3222117

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:07
User entered 'SICKD1'	System	17 Nov 2020 15:26:07

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:47:11
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:27:41

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:47:11
User entered '17 Nov 2020'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:27:41

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:47:11
User entered '09:18'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:27:41

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User entered '17 Nov 2020 09:18'	System	17 Nov 2020 15:27:41

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:47:11
User entered '172.7' cm	douglas winter (b) (4)	17 Nov 2020 15:27:41
DataPoint set to visible.	(b) (4) System	17 Nov 2020 15:26:07

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:47:11
User entered '135.6' kg	douglas winter (b) (4)	17 Nov 2020 15:27:41
DataPoint set to visible.	(b) (4) System	17 Nov 2020 15:26:07

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:47:11
User entered '36.7' C	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:27:41

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:47:11
User entered 'Oral (Oral)'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:27:41

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:47:11
User entered empty.	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:27:41

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:47:11
User entered '60'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:27:41

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User entered 'bpm'	System	17 Nov 2020 15:27:41

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:47:11
User entered '18'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:27:41

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User entered 'breaths/min'	System	17 Nov 2020 15:27:41

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:47:11
User entered '163'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:27:41

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User entered 'mmHg'	System	17 Nov 2020 15:27:41

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:47:11
User entered '84'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:27:41

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17
User entered 'mmHg'	System	17 Nov 2020 15:27:41

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17

US3222117

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:17

US3222117

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:47:20
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:27:55

US3222117

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:24
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:47:20
User entered '17 Nov 2020'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:27:55

US3222117

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:02:02

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:47:27
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:28:11

US3222117

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:02:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:31
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 17 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 09:15:03
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 17 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with '1f640292448' (Site from DM).	gail lavine (b) (4) (b) (4)	18 Jan 2021 14:23:24
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 17 NOV 2020 is recorded under illness Visit Day 1 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 12:33:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:47:27
User entered '17 Nov 2020'	douglas winter (b) (4) (b) (4)	17 Nov 2020 15:28:11

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:10:06
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:50:38

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:10:06
User entered '17 Dec 2020'	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:50:38

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:43
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:10:06
User entered 'Clinic (Clinic)'	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:50:38

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:43
User entered 'SICKD28'	System	16 Feb 2021 01:50:38

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:10:31
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:52:35

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:10:31
User entered '17 Dec 2020'	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:52:35

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 18:06:31
User closed query 'Source indicates this was 1345. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 18:06:29
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
Query 'Source indicates this was 1345. Please confirm and revise if necessary.' answered with 'confirmed 1345' (Site from CRA).	Diana Toney (b) (4)	22 Feb 2021 13:40:56
User entered '13:45' reason for change: Data Entry Error	(b) (4)	22 Feb 2021 13:40:43
User opened query 'Source indicates this was 1345. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:10:56
DataPoint Un-verified.	(b) (4), (b) (6)	19 Feb 2021 15:10:33
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 15:10:31
User entered '13:30'	douglas winter (b) (4)	16 Feb 2021 01:52:35
	(b) (4)	

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:51
User entered '17 Dec 2020 13:45'	System	22 Feb 2021 13:40:43
User entered '17 Dec 2020 13:30'	System	16 Feb 2021 01:52:35

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:10:31
User entered '172.7' cm	douglas winter (b) (4)	16 Feb 2021 01:52:35
DataPoint set to visible.	(b) (4) System	16 Feb 2021 01:50:38

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:10:31
User entered '137.1' kg	douglas winter (b) (4)	16 Feb 2021 01:52:35
DataPoint set to visible.	(b) (4) System	16 Feb 2021 01:50:38

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:10:31
User entered '36.9' C	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:52:35

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:10:31
User entered 'Oral (Oral)'	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:52:35

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:10:31
User entered empty.	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:52:35

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:10:31
User entered '70'	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:52:35

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:51
User entered 'bpm'	System	16 Feb 2021 01:52:35

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:10:31
User entered '20'	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:52:35

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:51
User entered 'breaths/min'	System	16 Feb 2021 01:52:35

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:10:31
User entered '178'	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:52:35

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:51
User entered 'mmHg'	System	16 Feb 2021 01:52:35

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:51
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 15:49:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:10:31
User entered '65'	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:52:35

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:51
User entered 'mmHg'	System	16 Feb 2021 01:52:35

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:51

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:02:02

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:51

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:11:10
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:52:49

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:02:02

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:30:58
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:11:10
User entered '17 Dec 2020'	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:52:49

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:02:02

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:12:03
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:53:06

US3222117

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:02:02

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:31:05
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:12:03
User entered '17 Dec 2020'	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:53:06

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 19:24:42

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '24 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 19:24:42

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 19:24:42

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:02:02

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered 'UNBLND_DECIDE'	System	24 Jan 2021 19:24:42

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '24 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 19:24:57

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 11:40:08
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:45:13

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 19:24:57

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 20:19:48
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 11:40:23
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	22 Apr 2021 11:40:08
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 07:36:39
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:45:13

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '24 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 19:24:57

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 19:24:57

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 19:24:57

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 19:24:57

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 19:24:57

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	24 Jan 2021 19:24:57

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:02:02

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered empty.	System	24 Jan 2021 19:24:57

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 24JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	24 Feb 2021 07:29:26
	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 24JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate. ' answered with 'ACCESSION: 1F66968 PER PRECLARUS WAS RECEIVED 02/FEB/2021.' (Site from DM).	douglas winter (b) (4)	19 Feb 2021 00:52:44
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 24JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 19:48:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Jan 2021 19:25:13

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '24 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 19:25:13

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '10:31'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 19:25:13

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:02:02

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered '24 Jan 2021 10:31'	System	24 Jan 2021 19:25:13

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:02:02

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 19:25:33

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:02:02

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '24 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 19:25:33

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:02:02

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '10:33'	(b) (4) (b) (4), (b) (6)	24 Jan 2021 19:25:33

US3222117

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:02:02

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:11:10
User entered '24 Jan 2021 10:33'	System	24 Jan 2021 19:25:33

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 16:02:02**

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:25:13
User entered '9 Dec 2020'	douglas winter (b) (4) (b) (4)	09 Dec 2020 16:01:19

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 16:02:02**

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:25:13
User entered 'l'	douglas winter (b) (4) (b) (4)	09 Dec 2020 16:01:19

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 16:02:02**

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:25:13
User entered '1'	douglas winter (b) (4) (b) (4)	09 Dec 2020 16:01:19

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 16:02:02**

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:25:13
User entered '0'	douglas winter (b) (4) (b) (4)	09 Dec 2020 16:01:19

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Unscheduled Visit Assessment**

Generated On: **09 Jun 2021 16:02:02**

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:47
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:25:13
User entered '0'	douglas winter (b) (4) (b) (4)	09 Dec 2020 16:01:19

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:02:02**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:25:33
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 16:03:47

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:02:02**

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:25:33
User entered '9 Dec 2020'	douglas winter (b) (4) (b) (4)	09 Dec 2020 16:03:47

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:02:02**

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:25:33
User entered '10:15'	douglas winter (b) (4) (b) (4)	09 Dec 2020 16:03:47

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:02:02**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:52
User entered '9 Dec 2020 10:15'	System	09 Dec 2020 16:03:47

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:02:02**

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:25:33
User entered '37.0' C	douglas winter (b) (4) (b) (4)	09 Dec 2020 16:03:47

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:02:02**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:25:33
User entered 'Oral (Oral)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 16:03:47

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:02:02**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:25:33
User entered empty.	douglas winter (b) (4) (b) (4)	09 Dec 2020 16:03:47

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:02:02**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:25:33
User entered '65'	douglas winter (b) (4) (b) (4)	09 Dec 2020 16:03:47

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:02:02**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:52
User entered 'bpm'	System	09 Dec 2020 16:03:47

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:02:02**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:25:33
User entered '20'	douglas winter (b) (4) (b) (4)	09 Dec 2020 16:03:47

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:02:02**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:52
User entered 'breaths/min'	System	09 Dec 2020 16:03:47

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:02:02**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:25:33
User entered '144'	douglas winter (b) (4) (b) (4)	09 Dec 2020 16:03:47

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:02:02**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:52
User entered 'mmHg'	System	09 Dec 2020 16:03:47

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:02:02**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:52
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:25:33
User entered '67'	douglas winter (b) (4) (b) (4)	09 Dec 2020 16:03:47

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:02:02**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:52
User entered 'mmHg'	System	09 Dec 2020 16:03:47

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:02:02**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:52

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Vital Signs**

Generated On: **09 Jun 2021 16:02:02**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:52

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Physical Examination**

Generated On: **09 Jun 2021 16:02:02**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:25:40
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	09 Dec 2020 16:03:55

US3222117

Folder: **Unscheduled 09 Dec 2020**

Form: **Physical Examination**

Generated On: **09 Jun 2021 16:02:02**

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:57
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:25:40
User entered '9 Dec 2020'	douglas winter (b) (4) (b) (4)	09 Dec 2020 16:03:55

US3222117

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:02:02

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:36:08
User closed query 'Per DM CLR: Per Safety Follow-up Diary Day 159, 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: Per Safety Follow-up Diary Day 159, 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 'SHE RECENTLY WAS DISCHARGED FROM THE HOSPITAL. (SAE)' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 11:42:30
User opened query 'Per DM CLR: Per Safety Follow-up Diary Day 159, 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 'SHE RECENTLY WAS DISCHARGED FROM THE HOSPITAL. (SAE)' (Site from DM).	douglas winter (b) (4) (b) (4)	12 Apr 2021 13:34:19
User opened query 'Per DM CLR: Per Safety Follow-up Diary Day 159, 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). User signature succeeded.	(b) (4), (b) (6)	02 Apr 2021 17:42:20
User closed query 'Please create AE source log for SAE for hospitalization around 11Dec2020.' (Site from CRA).	Bruce Rankin (b) (4) (b) (4) (b) (4), (b) (6)	19 Feb 2021 16:11:03
Query 'Please create AE source log for SAE for hospitalization around 11Dec2020.' answered with 'updated' (Site from CRA).	Diana Toney (b) (4) (b) (4)	02 Feb 2021 16:49:14
User opened query 'Please create AE source log for SAE for hospitalization around 11Dec2020.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 20:23:29
		19 Jan 2021 16:56:59

US3222117

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:02:02

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:47:57
User closed query 'Please reconcile and enter COVID-19 as central lab provided positive illness results' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 20:47:50
Query 'Please reconcile and enter COVID-19 as central lab provided positive illness results' answered with 'Added' (Site from CRA).	douglas winter (b) (4) (b) (4)	24 Nov 2020 13:48:34
User entered 'Yes (Y)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:11:19
User opened query 'Please reconcile and enter COVID-19 as central lab provided positive illness results' (Site from CRA).	(b) (4), (b) (6)	21 Nov 2020 16:57:27
User entered 'No (N)'	Amber Vasquez (b) (4) (b) (4)	09 Oct 2020 16:33:56

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:32
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:26
User entered 'USA-US104-2020-mRNA-1273-P301000021'	System	01 Dec 2020 16:34:22
User entered 'New'	(b) (4), (b) (6)	01 Dec 2020 16:34:22

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:29
User closed query 'Per CDM: Please consider updating the term to either Symptomatic Covid-19 or Covid-19' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 20:15:56
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 06:50:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Dec 2020 06:50:53
Data point term sent to Coder	System	01 Dec 2020 15:53:16
Query 'Per CDM: Please consider updating the term to either Symptomatic Covid-19 or Covid-19' answered with 'updated' (Site from DM).	gail lavine (b) (4) (b) (4)	01 Dec 2020 15:53:01
DataPoint Un-verified.	gail lavine (b) (4) (b) (4)	01 Dec 2020 15:52:46
Coding entries removed.	gail lavine (b) (4) (b) (4)	01 Dec 2020 15:52:46
User entered 'Covid-19.' reason for change: Data Entry Error	gail lavine (b) (4) (b) (4)	01 Dec 2020 15:52:46
User opened query 'Per CDM: Please consider updating the term to either Symptomatic Covid-19 or Covid-19' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 23:37:06
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:49:56
User closed query 'Please consider updating name to appropriate name of COVID-19' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 20:49:10
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:52:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:52:06
Data point term sent to Coder	System	24 Nov 2020 14:05:13
User entered 'POSITIVE COVID-19 RESULT FROM PCR.' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	24 Nov 2020 14:05:12
Query 'Please consider updating name to appropriate name of COVID-19' answered with 'Updated' (Site from CRA).	douglas winter (b) (4) (b) (4)	24 Nov 2020 14:03:18

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	24 Nov 2020 14:03:11
Coding entries removed.	douglas winter (b) (4)	24 Nov 2020 14:03:07
	(b) (4)	
User entered 'POSITIVE COVID-19 Result' reason for change: Data Entry Error	douglas winter (b) (4)	24 Nov 2020 14:03:07
	(b) (4)	
User opened query 'Please consider updating name to appropriate name of COVID-19' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:18:59
User coded data point as SOC: Investigations, HLGT: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: COVID-19 PCR test positive - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 14:16:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 14:16:57
	(b) (4)	
Data point term sent to Coder	System	23 Nov 2020 14:16:28
User entered 'POSITIVE COVID PCR'	douglas winter (b) (4)	23 Nov 2020 14:15:37
	(b) (4)	

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4)	24 Nov 2020 20:49:52
	(b) (4), (b) (6)	24 Nov 2020 20:49:52
User closed query 'Please reconcile as per protocol illness visit = MAAE' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 20:49:13
Query 'Please reconcile as per protocol illness visit = MAAE' answered with 'Updated' (Site from CRA).	douglas winter (b) (4)	24 Nov 2020 14:03:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	24 Nov 2020 14:03:07
	(b) (4)	24 Nov 2020 14:03:07
User opened query 'Please reconcile as per protocol illness visit = MAAE' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:19:13
User entered 'No (N)'	douglas winter (b) (4)	23 Nov 2020 14:15:37
	(b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4)	24 Nov 2020 20:49:50
	(b) (4), (b) (6)	
User closed query 'Please reconcile as this is well outside of the 7 days post dosing AR collection' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 20:49:18
Query 'Please reconcile as this is well outside of the 7 days post dosing AR collection' answered with 'Updated' (Site from CRA).	douglas winter (b) (4)	24 Nov 2020 14:03:32
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4)	24 Nov 2020 14:03:07
	(b) (4)	
User opened query 'Please reconcile as this is well outside of the 7 days post dosing AR collection' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:19:32
User entered 'Yes (Y)'	douglas winter (b) (4)	23 Nov 2020 14:15:37
	(b) (4)	

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:47
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:44
User entered '13 Nov 2020'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:42
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm start date as 13 Nov 2020 as no symptoms were reported until 17 Nov 2020' canceled (Site from Safety).	(b) (4), (b) (6)	17 Apr 2021 18:55:43
User opened query 'PV Query: Please confirm start date as 13 Nov 2020 as no symptoms were reported until 17 Nov 2020' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 17:53:19
User entered empty.	System	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User closed query 'Please enter end date on AE source log.' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 14:58:18
Query 'Please enter end date on AE source log.' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 14:06:20
User opened query 'Please enter end date on AE source log.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:53:31
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:52:58
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	26 Jan 2021 21:05:49
DataPoint Un-verified.	Diana Toney (b) (4)	26 Jan 2021 21:05:49
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Diana Toney (b) (4)	26 Jan 2021 21:05:49
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	26 Jan 2021 20:53:25
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:49:41
User entered 'Yes (Y)'	douglas winter (b) (4)	23 Nov 2020 14:15:37
	(b) (4)	

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:59:28
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 17:00:40
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	28 Jan 2021 02:27:23
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'Recovered/resolved' (Site from System).	Diana Toney (b) (4) (b) (4)	26 Jan 2021 21:05:34
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with '17 Dec 2020' (Site from Safety).	Diana Toney (b) (4) (b) (4)	26 Jan 2021 21:05:20
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Jan 2021 20:53:25
User entered '17 Dec 2020' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	26 Jan 2021 20:53:25
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 17:02:53
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 16:53:34
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:03:43
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:45
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:49:37
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:48
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:48
User entered '0'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:48
User entered '0'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:48
User entered '0'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:48
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:48
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:48
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:48
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:48
User entered '0'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:48
User entered '0'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:48
User entered '0'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:48
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:48
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:48
User entered 'Not Applicable (NOT APPLICABLE)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:48
User entered '1'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:48
User entered '0'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:48
User entered '0'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:04:34
User closed query 'AE source document does not have an entry for recovered/resolved. If correct, please enter it there.' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 15:04:32
User closed query 'Per CDM: Please verify the outcome as it is recorded as Recovering/Resolving, but end date is provided. Kindly review and update the response as recovered/resolved, Else clarify.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 09:47:33
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 17:00:45
Query 'Per CDM: Please verify the outcome as it is recorded as Recovering/Resolving, but end date is provided. Kindly review and update the response as recovered/resolved, Else clarify.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 14:06:50
Query 'AE source document does not have an entry for recovered/resolved. If correct, please enter it there.' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	09 Feb 2021 14:06:41
DataPoint Un-verified.	(b) (4), (b) (6)	09 Feb 2021 14:06:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 14:06:31
User opened query 'Per CDM: Please verify the outcome as it is recorded as Recovering/Resolving, but end date is provided. Kindly review and update the response as recovered/resolved, Else clarify.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 09:39:46
User opened query 'AE source document does not have an entry for recovered/resolved. If correct, please enter it there.' (Site from CRA).	(b) (4), (b) (6)	02 Feb 2021 16:57:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'recovered' (Site from Safety).	Diana Toney (b) (4) (b) (4)	26 Jan 2021 20:42:45
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 16:53:54
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:03:48
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:03:48
User entered empty.	douglas winter (b) (4) (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
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) (4), (b) (6)	09 Feb 2021 17:00:49
User closed query 'PV Query: Medical History of hypercholesterolemia is listed twice (onset 2005 and 2000). Please confirm the correct onset date and remove the duplicate entry.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 17:00:47
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 'pt took his own meds' (Site from Safety).	Diana Toney (b) (4) (b) (4)	26 Jan 2021 20:53:02
Query 'PV Query: Medical History of hypercholesterolemia is listed twice (onset 2005 and 2000). Please confirm the correct onset date and remove the duplicate entry.' answered with 'updated' (Site from Safety).	Diana Toney (b) (4) (b) (4)	26 Jan 2021 20:38:02
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)	08 Dec 2020 16:54:48
User opened query 'PV Query: Medical History of hypercholesterolemia is listed twice (onset 2005 and 2000). Please confirm the correct onset date and remove the duplicate entry.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 16:54:30
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:03:48

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

[Narrative](#)

Audit	User	Time (GMT)
User entered 'POSITIVE PCR FOR COVID-19 AND HE'S IS NOW ON TELEMEDICINE CALLS DAILY.' reason for change: Data Entry Error	douglas winter (b) (4)	24 Nov 2020 14:04:14
User entered 'POSITIVE PCR FOR COVID, HE'S ON TELEMEDICINE CALLS DAILY.'	douglas winter (b) (4)	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:02:02

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 14:03:07
User entered '0'	System	23 Nov 2020 14:15:37

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:40:55
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:13:20
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:13:14
Un-reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:10:44
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:49:32
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:40
User entered 'USA-US104-2020-mRNA-1273-P301000024'	System	14 Dec 2020 15:23:34
User entered 'New'	(b) (4), (b) (6)	14 Dec 2020 15:23:34

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH condition. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 10:39:12
User closed query 'Per MM, please clarify if this AE means COPD exacerbation. If so, please update event term as needed (subject has a reported MH of COPD in 2002) (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 10:39:09
User closed query 'PV Query: The event term CHRONIC OBSTRUCTIVE PULMONARY DISEASE/ CHRONIC LUNG DISEASE contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:40:40
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD exacerbation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 13:32:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 13:32:14
Query 'Per MM, please clarify if this AE means COPD exacerbation. If so, please update event term as needed (subject has a reported MH of COPD in 2002) answered with 'CORRECTED AE TERM' (Site from DM).	douglas winter (b) (4) (b) (4)	12 Apr 2021 13:31:53
Data point term sent to Coder Coding entries removed.	System douglas winter (b) (4) (b) (4)	12 Apr 2021 13:31:40 12 Apr 2021 13:31:34
User entered 'COPD EXACERBATION' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	12 Apr 2021 13:31:34

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease exacerbation - version MedDRA\23.0.	Coder Import (b) (4)	12 Apr 2021 13:28:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Apr 2021 13:28:55
Data point term sent to Coder	System	12 Apr 2021 13:28:38
Coding entries removed.	douglas winter (b) (4)	12 Apr 2021 13:27:51
User entered 'WORSENING CHRONIC OBSTRUCTIVE PULMONARY DISEASE' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 13:27:51
Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications.	douglas winter (b) (4)	12 Apr 2021 13:27:32
' answered with 'ADDED WORSENING TO AE TERM' (Site from DM).		
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4)	12 Apr 2021 13:24:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Apr 2021 13:24:59
Data point term sent to Coder	System	12 Apr 2021 13:24:37
Query 'PV Query: The event term CHRONIC OBSTRUCTIVE PULMONARY DISEASE/ CHRONIC LUNG DISEASE contains multiple event terms. Please consider separating them into separate events.' answered with 'CORRECTED AE TERM' (Site from Safety).	douglas winter (b) (4)	12 Apr 2021 13:24:35
DataPoint Un-verified.	douglas winter (b) (4)	12 Apr 2021 13:24:31
Coding entries removed.	douglas winter (b) (4)	12 Apr 2021 13:24:31
Signature has been broken.	douglas winter (b) (4)	12 Apr 2021 13:24:31

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 13:24:31
User opened query 'Per MM, please clarify if this AE means COPD exacerbation. If so, please update event term as needed (subject has a reported MH of COPD in 2002)' '(Site from DM).	(b) (4), (b) (6)	26 Mar 2021 13:34:05
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications.' '(Site from DM).	(b) (4), (b) (6)	11 Mar 2021 06:16:14
User opened query 'PV Query: The event term CHRONIC OBSTRUCTIVE PULMONARY DISEASE/ CHRONIC LUNG DISEASE contains multiple event terms. Please consider separating them into separate events.' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 16:14:20
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 16:40:53
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:31:35
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4)	02 Mar 2021 08:09:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	02 Mar 2021 08:09:17
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event/final diagnosis.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 17:19:22
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event/final diagnosis.' answered with 'Updated per medical records received for this Adverse Event' (Site from Safety).	(b) (4), (b) (6)	27 Feb 2021 18:27:43
Data point term sent to Coder	System	27 Feb 2021 18:27:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	27 Feb 2021 18:27:05
Coding entries removed.	(b) (4), (b) (6)	27 Feb 2021 18:27:05
Signature has been broken.	(b) (4), (b) (6)	27 Feb 2021 18:27:05
User entered 'Chronic Obstructive Pulmonary Disease/ Chronic Lung Disease' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Feb 2021 18:27:05
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event/final diagnosis.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 14:35:12
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 13:43:09
User closed query 'Per DM CLR: Please review if this AE is related to the recorded AE of Covid-19. If yes, please verify if these events should be combined as the dates are overlapping. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 13:42:54
Query 'Per DM CLR: Please review if this AE is related to the recorded AE of Covid-19. If yes, please verify if these events should be combined as the dates are overlapping. Please review and update applicable details as appropriate. Otherwise, clarify.' answered with 'SUBJECT HAS CHRONIC COPD, CONTINUES TO SMOKE, AND WAS POSITIVE COVID-19, AND ON MY CONVALESCENT SCHEDULE AND WAS AN SAE AND THEN DIAGNOSED WITH HAVING EXACERBATED SOB BECAUSE OF COVID-COPD.' (Site from DM).	douglas winter (b) (4) (b) (4)	19 Feb 2021 00:57:09

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' answered with 'HE WAS POSITIVE COVID-19 AND ON MY CONVALESCENT SCHEDULE AND WAS DIAGNOSED WITHIN HIS SAE AS HAVING COVID-COPD WHICH IS CAUSING INCREASED SOB' (Site from DM).	douglas winter (b) (4) (b) (4)	19 Feb 2021 00:55:10
User opened query 'Per MM, please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 18:30:34
User opened query 'Per DM CLR: Please review if this AE is related to the recorded AE of Covid-19. If yes, please verify if these events should be combined as the dates are overlapping. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 19:57:26
User closed query 'PV Query: Please confirm the event term(s). Paper SAE form reports the event as atrial fibrillation with RVR, however, the EDC reports the event as shortness of breath. Please update event term if needed or add additional event to EDC.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 13:29:42
Query 'PV Query: Please confirm the event term(s). Paper SAE form reports the event as atrial fibrillation with RVR, however, the EDC reports the event as shortness of breath. Please update event term if needed or add additional event to EDC.' answered with 'Confirmed Shortness of breath' (Site from Safety).	Diana Toney (b) (4) (b) (4)	26 Jan 2021 20:21:31
User opened query 'PV Query: Please confirm the event term(s). Paper SAE form reports the event as atrial fibrillation with RVR, however, the EDC reports the event as shortness of breath. Please update event term if needed or add additional event to EDC.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 17:16:06
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:49:35

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Dec 2020 18:22:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Dec 2020 18:22:53
Data point term sent to Coder	System	12 Dec 2020 18:21:43
User entered 'SHORTNESS OF BREATH'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:49:39
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:49:42
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:49:45
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:49:57
User entered '11 Dec 2020'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:05:51
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	12 Dec 2020 18:22:02
User entered empty; reason for change Data Entry Error	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:22:02
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	12 Dec 2020 18:21:32
User entered '18:02'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Dec 2020 18:22:02
User entered '11 Dec 2020 18:02'	System	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:05:45
DataPoint Un-verified.	Diana Toney (b) (4) (b) (4)	26 Jan 2021 20:14:11
User entered 'No (N)' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	26 Jan 2021 20:14:11
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:50:00
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4)	28 Jan 2021 15:05:47
	(b) (4), (b) (6)	28 Jan 2021 15:05:47
User closed query 'Source indicates subject was discharged 15Dec2020. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 15:05:43
Query 'Source indicates subject was discharged 15Dec2020. Please confirm and revise if necessary.' answered with 'confirmed ' (Site from CRA).	Diana Toney (b) (4)	26 Jan 2021 20:22:11
	(b) (4)	
User entered '15 Dec 2020' reason for change: Data Entry Error	Diana Toney (b) (4)	26 Jan 2021 20:14:11
	(b) (4)	
User opened query 'Source indicates subject was discharged 15Dec2020. Please confirm and revise if necessary.' (Site from CRA).	(b) (4), (b) (6)	20 Jan 2021 14:31:23
User entered empty.	douglas winter (b) (4)	12 Dec 2020 18:21:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:05:49
User entered empty.	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 18:42:49
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 17:14:56
User entered empty.	System	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:50:05
User entered 'Grade 3/Severe (Grade 3/Severe)'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:50:11
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	12 Dec 2020 18:22:02
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	12 Dec 2020 18:21:32
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:50:02
User entered '0'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:50:04
User entered '0'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	26 Dec 2020 11:21:59
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:50:30
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'UPDATED' (Site from System).	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:22:13
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		12 Dec 2020 18:22:02
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		12 Dec 2020 18:22:02
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	12 Dec 2020 18:22:02
User entered '1' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:22:02
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	12 Dec 2020 18:21:32
User entered '0'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:57:26
User entered '11 Dec 2020'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:50:11
User entered '15 Dec 2020' reason for change: Data Entry Error	Diana Toney (b) (4) (b) (4)	26 Jan 2021 20:14:11
User entered empty.	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:57:30
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:50:15
User entered empty.	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:50:16
User entered '0'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:50:18
User entered '0'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:50:21
User entered '0'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:57:34
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:57:36
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:57:37
User entered 'Not Applicable (NOT APPLICABLE)'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

None

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:50:33
User entered '0'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
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). User signature succeeded.	(b) (4), (b) (6)	22 Feb 2021 18:03:55
User closed query 'Per CDM: Per previous query response "Updated"; however, the update is not obvious please provide location such as log line number/data field updated. Thank you.' (Site from DM).	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
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 'UPDATED CONCOMITANT PAGE.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 11:26:35
Query 'Per CDM: Per previous query response "Updated"; however, the update is not obvious please provide location such as log line number/data field updated. Thank you.' answered with 'CONMED PAGE WAS UPDATED' (Site from DM).	douglas winter (b) (4) (b) (4)	19 Feb 2021 01:18:54
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). DataPoint Verified.	douglas winter (b) (4) (b) (4)	19 Feb 2021 01:10:32
	(b) (4), (b) (6)	04 Feb 2021 18:42:23
	(b) (4), (b) (6)	02 Feb 2021 16:52:30

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per previous query response "Updated"; however, the update is not obvious please provide location such as log line number/data field updated. Thank you. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 22:34:54
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 22:33:23
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Diana Toney (b) (4) (b) (4)	26 Jan 2021 20:22:25
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 06:05:50
User entered 'I'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:52:31
User entered '0'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Feb 2021 16:52:35
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 13:29:46
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'recovered/resolved' (Site from Safety).	Diana Toney (b) (4)	26 Jan 2021 20:22:41
DataPoint Un-verified.	(b) (4)	
	Diana Toney (b) (4)	26 Jan 2021 20:14:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4)	
	Diana Toney (b) (4)	26 Jan 2021 20:14:11
	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 17:15:10
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:58:03
User entered 'Unknown (UNKNOWN)'	douglas winter (b) (4)	12 Dec 2020 18:21:32
	(b) (4)	

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Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:52:37
User entered empty.	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: It was stated that the subject's SARS COV2 COVID-19 PCR was not detected. Please confirm when this test was performed.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 17:19:28
Query 'PV Query: It was stated that the subject's SARS COV2 COVID-19 PCR was not detected. Please confirm when this test was performed.'	(b) (4), (b) (6)	27 Feb 2021 19:06:06
answered with '25-Nov-2020' (Site from Safety).		
User opened query 'PV Query: It was stated that the subject's SARS COV2 COVID-19 PCR was not detected. Please confirm when this test was performed.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 14:34:46
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 18:04:03
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 18:04:00
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.'	(b) (4)	
answered with 'REDACTED SAE SUBMITTED' (Site from Safety).	douglas winter (b) (4)	19 Feb 2021 03:06:37
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.'	(b) (4)	
answered with 'SARS COV2 COVID-19 PCR NOT DETECTED.' (Site from Safety).	douglas winter (b) (4)	19 Feb 2021 01:20:34
	(b) (4)	

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 18:43:08
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Feb 2021 18:42:40
User closed query 'PV Query: Hypercholesterolemia is listed twice in medical history with conflicting start dates. Please confirm the start date.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 13:29:50
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)	27 Jan 2021 13:29:48
Query 'PV Query: Hypercholesterolemia is listed twice in medical history with conflicting start dates. Please confirm the start date.' answered with 'updated' (Site from Safety).	Diana Toney (b) (4) (b) (4)	26 Jan 2021 20:18:17
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 'updated' (Site from Safety).	Diana Toney (b) (4) (b) (4)	26 Jan 2021 20:15:34
User opened query 'PV Query: Hypercholesterolemia is listed twice in medical history with conflicting start dates. Please confirm the start date.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 17:15:44

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Narrative](#)

Audit	User	Time (GMT)
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)	18 Dec 2020 17:15:21
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 16:57:57
User entered 'I WAS INFORMED OF THE SAE AT 18:02 PM ON 11/DEC/2020. I SPOKE WITH THE PATIENT AND HIS WIFE DROVE HIM TO THE EMERGENCY ROOM AND THEY WILL EVALUATE WHY HE IS SHORT OF BREATH. HE HAS BEEN ON MY TELEMEDICINE CALLS SINCE 17/NOV/2020. I WILL CONTINUE TO CALL HIM EVERY NIGHT, AND HIS DAY 28 IS SCHEDULED FOR 15/DEC/2020. I WILL REQUEST RECORDS AFTER HE IS DISCHARGED.'	douglas winter (b) (4) (b) (4)	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	12 Dec 2020 18:21:32

US3222117

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:02:02

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Dec 2020 18:21:32

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:02:02

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:36:08
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per ETRTR: According to SAE "Shortness of Breath" (Atrial Fibrillation), medication was dosed but no medication is present in this folder. Please ensure adding ConMed dosed for SAE, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 15:06:24
Query 'Per ETRTR: According to SAE "Shortness of Breath" (Atrial Fibrillation), medication was dosed but no medication is present in this folder. Please ensure adding ConMed dosed for SAE, thanks.' answered with 'THE SUBJECT DID NOT HAVE AFIB. THAT WAS A TRANSCRIPTION ERROR. REDACTED MEDICAL RECORDS WERE UPLOADED TODAY.' (Site from CRA).	douglas winter (b) (4) (b) (4)	19 Feb 2021 03:08:39
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 16:51:03
User opened query 'Per ETRTR: According to SAE "Shortness of Breath" (Atrial Fibrillation), medication was dosed but no medication is present in this folder. Please ensure adding ConMed dosed for SAE, thanks.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 18:39:15
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:34:26

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Oct 2020 16:41:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:41:08
Data point term sent to Coder	System	07 Oct 2020 16:39:29
User entered 'LANTUS'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:38:30

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) gail lavine (b) (4)	01 Dec 2020 16:00:12
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4)	07 Oct 2020 16:38:30

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'DIABETES'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:38:30

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. Also, please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 10:32:36
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. Also, please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' answered with 'Corrected dosage' (Site from DM).	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:40:16
User entered '40' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:40:00
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. Also, please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 17:33:56
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' canceled (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 17:33:27
Query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 17:33:20
User opened query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 17:32:53
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 17:32:33

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '35 U/45 U'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:38:30

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'IU (IU)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:38:30

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:38:30

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'twice daily (BID)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:38:30

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:38:30

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Albert Garcia (b) (4)	07 Oct 2020 16:38:30

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:38:30

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'UN UNK 2013'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:38:30

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:38:30

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:38:30

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:38:30

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:38:30

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Oct 2020 16:38:30

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:38:30

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 16:38:30

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	07 Oct 2020 16:41:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:41:08
Data point term sent to Coder	System	07 Oct 2020 16:39:29
User entered 'NOVOLOG'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:19

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) gail lavine (b) (4)	01 Dec 2020 16:00:47
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4)	07 Oct 2020 16:39:19

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'DIABETES'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:19

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'SLIDING SCALE'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:19

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'IU (IU)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:19

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:19

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'as needed (PRN)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:19

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:19

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) Albert Garcia (b) (4)	07 Oct 2020 16:39:19

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:19

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'UN UNK 2013'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:19

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:19

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:19

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:19

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:19

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 16:39:19

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 16:39:19

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 16:39:19

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Oct 2020 06:05:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 06:05:25
Data point term sent to Coder	System	07 Oct 2020 16:40:30
User entered 'LASIX'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:56

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) gail lavine (b) (4)	01 Dec 2020 15:54:40
User entered 'Yes (Y)'	(b) (4) Albert Garcia (b) (4)	07 Oct 2020 16:39:56

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'COPD'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:56

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 20:53:49
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:22:02
User entered 'UNK' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:21:43
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 01:44:53
User entered '1'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:56

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Albert Garcia (b) (4)	03 Dec 2020 15:21:57
	(b) (4)	
User entered 'tablet (TABLET)'	Albert Garcia (b) (4)	07 Oct 2020 16:39:56
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:56

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'once daily (QD)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:56

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:56

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:56

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:56

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered 'UN UNK 2017'	Albert Garcia (b) (4)	07 Oct 2020 16:39:56
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:56

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:56

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:56

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:39:56

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:39:56

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:39:56

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 16:39:56

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Dec 2020 15:23:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Dec 2020 15:23:59
Data point term sent to Coder Coding entries removed.	System Albert Garcia (b) (4)	03 Dec 2020 15:22:48 03 Dec 2020 15:22:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 16:43:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 16:43:30
Data point term sent to Coder User entered 'SINGULAIR'	System Albert Garcia (b) (4)	07 Oct 2020 16:40:30 07 Oct 2020 16:40:23

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) gail lavine (b) (4)	01 Dec 2020 16:02:54
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' canceled (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 01:49:57
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 01:46:53
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:40:23

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per CDM: Response noted. However, there is no corresponding Medical History record. Please update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 20:55:01
User closed query 'Per CDM CR: Please update the indication to reflect the location and type of ALLERGIES, (e.g SEASONAL ALLERGIES, FOOD ALLERGY, DRUG ALLERGY etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 20:54:59
Query 'Per CDM: Response noted. However, there is no corresponding Medical History record. Please update as appropriate.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	11 Dec 2020 14:08:01
User opened query 'Per CDM: Response noted. However, there is no corresponding Medical History record. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 13:34:16
Query 'Per CDM CR: Please update the indication to reflect the location and type of ALLERGIES, (e.g SEASONAL ALLERGIES, FOOD ALLERGY, DRUG ALLERGY etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:22:27
User entered 'ALLERGIES - SEASONAL' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:22:22
User opened query 'Per CDM CR: Please update the indication to reflect the location and type of ALLERGIES, (e.g SEASONAL ALLERGIES, FOOD ALLERGY, DRUG ALLERGY etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 01:45:27
User entered 'ALLERGIES'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:40:23

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 10:33:13
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Corrected dosage' (Site from DM).	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:41:48
User entered '10' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:41:30
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 17:34:45
User entered '25'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:40:23

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:40:23

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:40:23

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'once daily (QD)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:40:23

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:40:23

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:40:23

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:40:23

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'UN UNK 2002'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:40:23

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:40:23

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:40:23

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:40:23

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:40:23

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:40:23

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:40:23

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 16:40:23

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: BISOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Oct 2020 16:45:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:45:37
Data point term sent to Coder	System	07 Oct 2020 16:41:32
User entered 'BISOPROLOL'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:04

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:29:46
Query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:22:46
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:22:41
User opened query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 03:22:24
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:04

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'HYPERTENSION'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:04

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '5'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:04

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:04

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:04

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'once daily (QD)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:04

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:04

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:04

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:04

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered 'UN UNK 2004'	Albert Garcia (b) (4)	07 Oct 2020 16:41:04
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:04

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:04

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:04

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:04

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:41:04

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:41:04

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 16:41:04

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Dec 2020 15:25:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Dec 2020 15:25:05
Data point term sent to Coder Coding entries removed.	System Albert Garcia (b) (4)	03 Dec 2020 15:23:48 03 Dec 2020 15:23:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 16:47:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 16:47:02
Data point term sent to Coder User entered 'PLAVIX'	System Albert Garcia (b) (4)	07 Oct 2020 16:42:33 07 Oct 2020 16:41:33

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:33

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Please update the indication of this medication to an actual medical condition rather than the drug class, (e.g STROKE PROPHYLAXIS etc). Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 20:55:26
Query 'Per DM CLR: Please update the indication of this medication to an actual medical condition rather than the drug class, (e.g STROKE PROPHYLAXIS etc). Update Con Med eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:23:29
User entered 'BLOOD CLOT PREVENTION' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:23:25
User opened query 'Per DM CLR: Please update the indication of this medication to an actual medical condition rather than the drug class, (e.g STROKE PROPHYLAXIS etc). Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 01:59:19
User entered 'BLOOD THINNER'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:33

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 10:35:05
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Corrected dosage' (Site from DM).	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:37:08
User entered '75' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	16 Feb 2021 01:36:55
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 17:35:18
User entered '25'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:33

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:33

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:33

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'once daily (QD)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:33

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:33

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:33

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:33

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered 'UN UNK 2016'	Albert Garcia (b) (4)	07 Oct 2020 16:41:33
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:33

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:33

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:33

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:41:33

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:41:33

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:41:33

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 16:41:33

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Oct 2020 16:47:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:47:03
Data point term sent to Coder	System	07 Oct 2020 16:42:33
User entered 'LISINOPRIL'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:00

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:29:58
Query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:23:47
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:23:42
User opened query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 03:22:46
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:00

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'HYPERTENSION'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:00

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '20'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:00

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:00

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:00

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'twice daily (BID)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Oct 2020 14:31:35
User entered 'once daily (QD)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:00

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:00

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:00

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:00

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM -RQ: Please verify that concomitant medication start date (UN UNK 1990) is prior to the Medical history start date (UN UNK 1991). Please review Con Med and MH start dates and update accordingly. Else clarify.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	03 Mar 2021 09:57:14
Query 'Per CDM -RQ: Please verify that concomitant medication start date (UN UNK 1990) is prior to the Medical history start date (UN UNK 1991). Please review Con Med and MH start dates and update accordingly. Else clarify.' answered with 'CORRECTED TO 1991' (Site from DM). Signature has been broken.	Vicki Miller (b) (4) (b) (4) douglas winter (b) (4) (b) (4)	02 Mar 2021 21:31:35 02 Mar 2021 17:08:07 02 Mar 2021 17:07:56
User entered 'UN UNK 1991' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	02 Mar 2021 17:07:56
User opened query 'Per CDM -RQ: Please verify that concomitant medication start date (UN UNK 1990) is prior to the Medical history start date (UN UNK 1991). Please review Con Med and MH start dates and update accordingly. Else clarify.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:32:12
User closed query 'Per DM CLR re-query: Response is noted, however, Con Med start date is still prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:32:12
Query 'Per DM CLR re-query: Response is noted, however, Con Med start date is still prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'Reconciled both Con med and MH dates ' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 18:38:40
User opened query 'Per DM CLR re-query: Response is noted, however, Con Med start date is still prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 15:13:29
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UNK 1991). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM). Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UNK 1991). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' answered with 'Corrected date' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 10:35:38
User entered 'UN UNK 1990' reason for change: Data Entry Error	douglas winter (b) (4)	16 Feb 2021 01:44:02
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UNK 1991). Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4)	16 Feb 2021 01:43:51
User entered 'UN UNK 1988'	(b) (4), (b) (6)	28 Jan 2021 17:36:04
User entered 'UN UNK 1988'	Albert Garcia (b) (4)	07 Oct 2020 16:42:00

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:00

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:00

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:00

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:00

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Oct 2020 14:31:35
User entered '1'	System	07 Oct 2020 16:42:00

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:42:00

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 16:42:00

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Oct 2020 16:47:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:47:02
Data point term sent to Coder	System	07 Oct 2020 16:42:34
User entered 'SPIRONOLACTONE'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:31

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:30:23
Query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:24:13
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:24:09
User opened query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 03:23:00
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:31

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'HYPERTENSION'	Albert Garcia (b) (4)	07 Oct 2020 16:42:31

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '25'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:31

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:31

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:31

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'once daily (QD)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:31

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:31

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:31

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:31

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered 'UN UNK 2016'	Albert Garcia (b) (4)	07 Oct 2020 16:42:31
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:31

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:31

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:31

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:42:31

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:42:31

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:42:31

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 16:42:31

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	07 Oct 2020 16:49:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:49:30
Data point term sent to Coder	System	07 Oct 2020 16:43:35
User entered 'ADVAIR'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:30:33
Query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:24:37
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:24:26
User opened query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 03:23:45
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'COPD'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '250/50'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Other (OTHER)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'MCGS'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered 'twice daily (BID)'	Albert Garcia (b) (4)	07 Oct 2020 16:43:17
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'UN UNK 2002'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	07 Oct 2020 16:43:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:43:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 16:43:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 16:50:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 16:50:48
Data point term sent to Coder	System	07 Oct 2020 16:44:36
User entered 'ASPIRIN'	Albert Garcia (b) (4)	07 Oct 2020 16:43:46

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:46

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered 'CARDIAC SUPPLEMENT'	Albert Garcia (b) (4)	07 Oct 2020 16:43:46
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '81'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:46

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:46

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:46

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'once daily (QD)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:46

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:46

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:46

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:46

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'UN UNK 1980'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:46

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:46

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:46

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:46

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:43:46

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:43:46

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:43:46

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 16:43:46

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Oct 2020 13:50:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 13:50:41
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	20 Oct 2020 16:14:20 20 Oct 2020 16:13:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 16:50:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 16:50:50
Data point term sent to Coder User entered 'GABAPENTIN'	System Albert Garcia (b) (4)	07 Oct 2020 16:44:37 07 Oct 2020 16:44:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 08:59:14
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 16:30:58
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 16:30:47
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 23:01:08
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per CDM: Please update indication to include location, type, and whether sensory/motor. Ensure that there is a corresponding Med Hist/AE record that match the updated indication. Please update applicable details as appropriate or, provide further clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 09:30:04
Query 'Per CDM: Please update indication to include location, type, and whether sensory/motor. Ensure that there is a corresponding Med Hist/AE record that match the updated indication. Please update applicable details as appropriate or, provide further clarification.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 16:14:04
User entered 'Diabetic NEUROPATHY - (Hands and feet)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 16:13:58
User opened query 'Per CDM: Please update indication to include location, type, and whether sensory/motor. Ensure that there is a corresponding Med Hist/AE record that match the updated indication. Please update applicable details as appropriate or, provide further clarification.' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 15:26:30
User entered 'NEUROPATHY'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '300'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'three times daily (TID)'	(b) (4) Albert Garcia (b) (4)	07 Oct 2020 16:44:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'UN UNK 2010'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	07 Oct 2020 16:44:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:44:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 16:44:17

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Oct 2020 16:50:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:50:51
Data point term sent to Coder	System	07 Oct 2020 16:45:38
User entered 'ROSUVASTATIN'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:44

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:30:54
Query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:24:53
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:24:49
User opened query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 03:25:52
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:44

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'HYPERCHOLESTERLEMIA'	(b) (4) Albert Garcia (b) (4)	07 Oct 2020 16:44:44

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '20'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:44

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:44

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:44

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'once daily (QD)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:44

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:44

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:44

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:44

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'UN UNK 2000'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:44

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:44

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:44

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:44

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:44:44

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:44:44

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:44:44

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 16:44:44

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: PRAMIPEXOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Dec 2020 16:33:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Dec 2020 16:33:25
Data point term sent to Coder Coding entries removed.	System Albert Garcia (b) (4)	28 Dec 2020 16:32:40 28 Dec 2020 16:32:14
User entered 'Pramipexole' reason for change: Data Entry Error	Albert Garcia (b) (4)	28 Dec 2020 16:32:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: PRAMIPEXOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 19:54:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 19:54:49
Data point term sent to Coder User entered 'PRAMIPEXOLE'	System Albert Garcia (b) (4)	07 Oct 2020 16:46:40 07 Oct 2020 16:45:40

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:31:04
Query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:25:10
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:25:06
User opened query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 03:25:59
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:45:40

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'RESTLESS LEG SYNDROME'	(b) (4) Albert Garcia (b) (4)	07 Oct 2020 16:45:40

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 11:30:51
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 16:34:33
User entered '1.5' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	28 Dec 2020 16:34:21
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 00:28:32
User entered '.015' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 14:32:45
User entered '.05'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:45:40

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:45:40

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:45:40

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'once daily (QD)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:45:40

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:45:40

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered 'Oral (ORAL)'	Albert Garcia (b) (4)	07 Oct 2020 16:45:40
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:45:40

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered 'UN UNK 2015'	Albert Garcia (b) (4)	07 Oct 2020 16:45:40
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:45:40

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:45:40

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:45:40

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:45:40

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:45:40

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:45:40

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 16:45:40

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Feb 2021 01:52:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Feb 2021 01:52:00
Data point term sent to Coder Coding entries removed.	System douglas winter (b) (4)	19 Feb 2021 01:51:38 19 Feb 2021 01:50:47
User entered 'TRAZODONE' reason for change: Data Entry Error	douglas winter (b) (4)	19 Feb 2021 01:50:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 16:52:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 16:52:12
Data point term sent to Coder	System	07 Oct 2020 16:46:40
User entered 'TRAZADONE'	Albert Garcia (b) (4)	07 Oct 2020 16:46:05

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 12:31:12
Query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:25:29
User entered 'No (N)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	03 Dec 2020 15:25:24
User opened query 'Per DM CLR: Indication = Prophylaxis. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 03:26:06
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:46:05

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered 'INSOMNIA'	Albert Garcia (b) (4)	07 Oct 2020 16:46:05
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 11:27:09
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'CORRECTED DOSE FROM 20 TO 25' (Site from DM).	douglas winter (b) (4) (b) (4)	19 Feb 2021 01:51:03
User entered '25' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	19 Feb 2021 01:50:47
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 17:38:24
User entered '20'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:46:05

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'mg (mg)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:46:05

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:46:05

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'once daily (QD)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:46:05

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:46:05

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Oral (ORAL)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:46:05

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:46:05

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered 'UN UNK 2015'	Albert Garcia (b) (4)	07 Oct 2020 16:46:05
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered '0'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:46:05

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:46:05

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered empty.	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:46:05

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 16:46:05

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:46:05

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 16:46:05

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 16:46:05

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:02:02

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 12:36:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 12:36:50
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	27 Feb 2021 18:46:34 27 Feb 2021 18:46:15
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 07:20:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 07:20:08
Data point term sent to Coder User entered 'ACETAMINOPHEN-HYDROCODONE'	System douglas winter (b) (4) (b) (4)	19 Feb 2021 01:04:24 19 Feb 2021 01:04:18

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:55
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:16:17
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 09:59:58
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'given as treatment not prophylaxis' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 14:27:12
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 14:26:49
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Mar 2021 14:26:49
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 07:23:19
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4) (b) (4)	19 Feb 2021 01:04:18

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:55
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:31:35
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Mar 2021 11:34:12
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'Updated per medical records received for SAE' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 18:46:21
Signature has been broken.	(b) (4), (b) (6)	27 Feb 2021 18:46:15
User entered 'Chest pain/ Chronic Obstructive Pulmonary Disease' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Feb 2021 18:46:15
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 15:13:46
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'NON-ACUTE MODERATE PAIN.'	(b) (4) douglas winter (b) (4) (b) (4)	19 Feb 2021 01:04:18

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '325-7.5'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:04:18

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:55
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	19 Feb 2021 01:04:18

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:04:18

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'as needed (PRN)'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:04:18

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:04:18

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:04:18
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:04:18

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '11 Dec 2020'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:04:18
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '0'	(b) (4) douglas winter (b) (4) (b) (4)	19 Feb 2021 01:04:18

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:04:18

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '12 Dec 2020'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:04:18
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:04:18

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:55
User entered empty.	System	19 Feb 2021 01:04:18

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:55
User entered empty.	System	19 Feb 2021 01:04:18

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:09:55
User entered empty.	System	19 Feb 2021 01:04:18

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:26:56
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: SECOND-GENERATION CEPHALOSPORINS, PRODUCT: CEFUROXIME - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	19 Feb 2021 07:28:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 07:28:03
Data point term sent to Coder User entered 'CEFUROXIME'	System douglas winter (b) (4) (b) (4)	19 Feb 2021 01:06:25 19 Feb 2021 01:06:09

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:26:56
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Yes (Y)'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:06:09
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:26:56
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'per medical records received for SAE, cefuroxime was prescribed for bacterial infection. SAE was done under chronic obstructive pulmonary disease/ chest pain/ chronic lung disease.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 11:34:36
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'per medical records received for SAE, cefuroxime was prescribed for bacterial infection. SAE was done under chronic obstructive pulmonary disease/ chest pain/ chronic lung disease.' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 19:24:38
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 15:13:55
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'BACTERIAL INFECTION'	(b) (4) douglas winter (b) (4) (b) (4)	19 Feb 2021 01:06:09

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:26:56
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '500'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:06:09
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:26:56
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'mg (mg)'	douglas winter (b) (4) (b) (4)	19 Feb 2021 01:06:09

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:26:56
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:06:09
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:26:56
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'other (OTHER)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	19 Feb 2021 01:09:30
User entered 'twice daily (BID)'	douglas winter (b) (4) (b) (4)	19 Feb 2021 01:06:09

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:26:56
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered 'BID FOR 7 DAYS' reason for change: douglas winter	(b) (4)	19 Feb 2021 01:09:30
Data Entry Error	(b) (4)	
User entered empty.	douglas winter (b) (4)	19 Feb 2021 01:06:09
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:26:56
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:06:09
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:26:56
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:06:09
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:26:56
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '11 Dec 2020'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:06:09
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:26:56
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '0'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:06:09
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:26:56
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)' reason for change: Data Entry Error	douglas winter (b) (4) (b) (4)	19 Feb 2021 01:09:30
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	19 Feb 2021 01:06:09

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:26:56
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered '17 Dec 2020' reason for change: Data Entry Error	douglas winter (b) (4)	19 Feb 2021 01:09:30
	(b) (4)	
User entered empty.	douglas winter (b) (4)	19 Feb 2021 01:06:09
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:26:56
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:06:09
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:26:56
User entered empty.	System	19 Feb 2021 01:09:30
User entered '2'	System	19 Feb 2021 01:06:09

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:26:56
User entered empty.	System	19 Feb 2021 01:09:30
User entered '1'	System	19 Feb 2021 01:06:09

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:26:56
User entered empty.	System	19 Feb 2021 01:09:30
User entered '804 (804)'	System	19 Feb 2021 01:06:09

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:27:02
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISON - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:33:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:33:09
User signature succeeded.	Bruce Rankin (b) (4) (b) (4)	19 Feb 2021 16:11:03
Data point term sent to Coder	System	19 Feb 2021 01:08:26
User entered 'PREDNISON'	douglas winter (b) (4) (b) (4)	19 Feb 2021 01:08:12

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:08:12
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'SHORTNESS OF BREATH'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:08:12
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '20'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:08:12

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'mg (mg)'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:08:12
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:08:12
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'other (OTHER)'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:08:12

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'BID X 3 DAYS'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:08:12
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'Oral (ORAL)'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:08:12
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered empty.	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:08:12
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '11 Dec 2020'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:08:12
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '0'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:08:12
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:08:12
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '13 Dec 2020'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:08:12
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:27:02
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'No (N)'	(b) (4) douglas winter (b) (4)	19 Feb 2021 01:08:12
	(b) (4)	

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:27:02
User entered empty.	System	19 Feb 2021 01:08:12

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:27:02
User entered empty.	System	19 Feb 2021 01:08:12

US3222117

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:02:02

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 13:27:02
User entered empty.	System	19 Feb 2021 01:08:12

US3222117

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:02:02

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	09 Oct 2020 16:34:13
	(b) (4)	

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'USA-US104-2020-MRNA-1273-P301000021'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:19:26
User closed query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 15:19:22
Query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:23:09
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User entered 'Bruce' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User opened query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 19:04:00
Query 'Where did the information come for the investigator? This subject is from site 322, Dr. Bruce Rankin. Upon reviewing the audit history, it says it's coming from "system". ' canceled (DM from CRA).	(b) (4), (b) (6)	29 Mar 2021 19:03:54
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:01:04
User opened query 'Where did the information come for the investigator? This subject is from site 322, Dr. Bruce Rankin. Upon reviewing the audit history, it says it's coming from "system". ' (DM from CRA).	(b) (4), (b) (6)	02 Feb 2021 17:02:01
Un-reviewed for Safety.	System	14 Dec 2020 15:23:34
DataPoint Un-verified.	System	14 Dec 2020 15:23:34
User entered 'Teresa'	System	14 Dec 2020 15:23:34
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'Lisa'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:19:26
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User entered 'Rankin' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:01:04
Un-reviewed for Safety.	System	14 Dec 2020 15:23:34
DataPoint Un-verified.	System	14 Dec 2020 15:23:34
User entered 'Becker'	System	14 Dec 2020 15:23:34
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'Holloway'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:15
DataPoint Un-verified.	System	13 Apr 2021 17:41:46
User entered '860 Peachwood Ave'	System	13 Apr 2021 17:41:46
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:26
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User entered '860 Peachwood Drive' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:33:22
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered '6550 Mapleridge Street'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:16
DataPoint Un-verified.	System	13 Apr 2021 17:41:46
User entered 'Deland'	System	13 Apr 2021 17:41:46
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:26
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User entered 'HOUSTONDeland' reason for change:	(b) (4), (b) (6)	08 Apr 2021 16:22:50
Data Entry Error		
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:33:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'Houston'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:01:04
Un-reviewed for Safety.	System	14 Dec 2020 15:23:34
DataPoint Un-verified.	System	14 Dec 2020 15:23:34
User entered empty.	System	14 Dec 2020 15:23:34
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'TX'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:19:26
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User entered '32720' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:33:26
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered '77081'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:01:04
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 16:33:27
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
User entered 'US'	System	01 Dec 2020 16:34:45

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '2'	(b) (4)	09 Feb 2021 17:01:15
User entered '1'	System	01 Dec 2020 16:34:45

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'USA-US104-2020-MRNA-1273-P301000021'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:19:26
User closed query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 15:19:22
Query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:23:09
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User entered 'Bruce' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User opened query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 19:04:00
Query 'Where did the information come for the investigator? This subject is from site 322, Dr. Bruce Rankin. Upon reviewing the audit history, it says it's coming from "system". ' canceled (DM from CRA).	(b) (4), (b) (6)	29 Mar 2021 19:03:54
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:01:04
User opened query 'Where did the information come for the investigator? This subject is from site 322, Dr. Bruce Rankin. Upon reviewing the audit history, it says it's coming from "system". ' (DM from CRA).	(b) (4), (b) (6)	02 Feb 2021 17:02:01
Un-reviewed for Safety.	System	14 Dec 2020 15:23:34
DataPoint Un-verified.	System	14 Dec 2020 15:23:34
User entered 'Teresa'	System	14 Dec 2020 15:23:34
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'Lisa'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:19:26
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User entered 'Rankin' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:01:04
Un-reviewed for Safety.	System	14 Dec 2020 15:23:34
DataPoint Un-verified.	System	14 Dec 2020 15:23:34
User entered 'Becker'	System	14 Dec 2020 15:23:34
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'Holloway'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:15
DataPoint Un-verified.	System	13 Apr 2021 17:41:46
User entered '860 Peachwood Ave'	System	13 Apr 2021 17:41:46
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:26
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User entered '860 Peachwood Drive' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:33:22
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered '6550 Mapleridge Street'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:16
DataPoint Un-verified.	System	13 Apr 2021 17:41:46
User entered 'Deland'	System	13 Apr 2021 17:41:46
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:26
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User entered 'HOUSTONDeland' reason for change:	(b) (4), (b) (6)	08 Apr 2021 16:22:50
Data Entry Error		
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:33:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'Houston'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:01:04
Un-reviewed for Safety.	System	14 Dec 2020 15:23:34
DataPoint Un-verified.	System	14 Dec 2020 15:23:34
User entered empty.	System	14 Dec 2020 15:23:34
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'TX'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:19:26
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User entered '32720' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:33:26
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered '77081'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:01:04
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 16:33:27
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
User entered 'US'	System	01 Dec 2020 16:34:45

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '2'	(b) (4)	09 Feb 2021 17:01:15
User entered '1'	System	01 Dec 2020 16:34:45

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:02:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
User entered '01/Dec/2020 16:34'	System	01 Dec 2020 16:34:45

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:02:02

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:01:04
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
User entered '1'	(b) (4), (b) (6)	01 Dec 2020 16:34:45

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'USA-US104-2020-MRNA-1273-P301000021'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'No (N)'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4)	09 Apr 2021 15:19:26
	(b) (4), (b) (6)	
User closed query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 15:19:22
Query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:23:09
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User entered 'Bruce' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User opened query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 19:04:00
Query 'Where did the information come for the investigator? This subject is from site 322, Dr. Bruce Rankin. Upon reviewing the audit history, it says it's coming from "system". ' canceled (DM from CRA).	(b) (4), (b) (6)	29 Mar 2021 19:03:54
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4)	09 Feb 2021 17:01:04
	(b) (4), (b) (6)	
User opened query 'Where did the information come for the investigator? This subject is from site 322, Dr. Bruce Rankin. Upon reviewing the audit history, it says it's coming from "system". ' (DM from CRA).	(b) (4), (b) (6)	02 Feb 2021 17:02:01
Un-reviewed for Safety.	System	14 Dec 2020 15:23:34
DataPoint Un-verified.	System	14 Dec 2020 15:23:34
User entered 'Teresa'	System	14 Dec 2020 15:23:34
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'Lisa'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:19:26
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User entered 'Rankin' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:01:04
Un-reviewed for Safety.	System	14 Dec 2020 15:23:34
DataPoint Un-verified.	System	14 Dec 2020 15:23:34
User entered 'Becker'	System	14 Dec 2020 15:23:34
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'Holloway'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4)	20 Apr 2021 16:08:15
DataPoint Un-verified.	(b) (4), (b) (6)	
User entered '860 Peachwood Ave'	System	13 Apr 2021 17:41:46
DataPoint Verified.	System	13 Apr 2021 17:41:46
	(b) (4), (b) (6)	09 Apr 2021 15:19:26
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User entered '860 Peachwood Drive' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Un-verified.	(b) (4)	15 Dec 2020 16:33:22
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered '6550 Mapleridge Street'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:16
DataPoint Un-verified.	System	13 Apr 2021 17:41:46
User entered 'Deland'	System	13 Apr 2021 17:41:46
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:26
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User entered 'HOUSTONDeland' reason for change:	(b) (4), (b) (6)	08 Apr 2021 16:22:50
Data Entry Error		
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:33:25
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'Houston'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:01:04
Un-reviewed for Safety.	System	14 Dec 2020 15:23:34
DataPoint Un-verified.	System	14 Dec 2020 15:23:34
User entered empty.	System	14 Dec 2020 15:23:34
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered 'TX'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:19:26
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User entered '32720' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:22:50
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:33:26
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 16:34:40
User entered '77081'	System	01 Dec 2020 16:34:22

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:01:04
DataPoint Un-verified.	(b) (4), (b) (6)	15 Dec 2020 16:33:27
DataPoint Verified.	(b) (4), (b) (6)	11 Dec 2020 19:40:57
User entered 'US'	System	01 Dec 2020 16:34:45

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '2'	(b) (4)	09 Feb 2021 17:01:15
User entered '1'	System	01 Dec 2020 16:34:45

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:02:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '09/Feb/2021 12:01'	(b) (4) System	09 Feb 2021 17:01:15

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000021

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:02:02

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:01:15

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:45:57
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'USA-US104-2020-MRNA-1273-P301000024'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:00
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Yes (Y)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:01
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:03
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Yes (Y)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:09
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:11
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:13
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User closed query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 15:19:34
Query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:24:41
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered 'Bruce' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User opened query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 19:04:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Teresa'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered 'Rankin' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Becker'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:32
Un-reviewed for Safety.	System	13 Apr 2021 17:41:46
DataPoint Un-verified.	System	13 Apr 2021 17:41:46
User entered '860 Peachwood Ave'	System	13 Apr 2021 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered '860 Peachwood Dr' reason for change:	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Data Entry Error		
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered '6550 Mapleridge Street'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered 'Deland' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Houston'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 16:24:13

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered '32720' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered '77081'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 13:30:02
User entered 'US'	System	14 Dec 2020 15:23:59

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	13 Apr 2021 17:41:46
User entered '4'	System	01 Mar 2021 17:19:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:19:47
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 18:04:50
User entered '3'	System	22 Feb 2021 18:04:50
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered '2'	System	27 Jan 2021 13:30:11
User entered '1'	System	14 Dec 2020 15:23:59

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:45:57
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'USA-US104-2020-MRNA-1273-P301000024'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:00
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Yes (Y)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:01
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:03
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Yes (Y)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:09
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:11
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:13
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User closed query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 15:19:34
Query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:24:41
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered 'Bruce' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User opened query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 19:04:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Teresa'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered 'Rankin' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Becker'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:32
Un-reviewed for Safety.	System	13 Apr 2021 17:41:46
DataPoint Un-verified.	System	13 Apr 2021 17:41:46
User entered '860 Peachwood Ave'	System	13 Apr 2021 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered '860 Peachwood Dr' reason for change:	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Data Entry Error		
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered '6550 Mapleridge Street'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered 'Deland' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Houston'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 16:24:13

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered '32720' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered '77081'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 13:30:02
User entered 'US'	System	14 Dec 2020 15:23:59

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	13 Apr 2021 17:41:46
User entered '4'	System	01 Mar 2021 17:19:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:19:47
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 18:04:50
User entered '3'	System	22 Feb 2021 18:04:50
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered '2'	System	27 Jan 2021 13:30:11
User entered '1'	System	14 Dec 2020 15:23:59

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:02:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '14/Dec/2020 10:23'	(b) (4) System	14 Dec 2020 15:23:59

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:02:02

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 13:30:02
User entered 'I'	(b) (4), (b) (6)	14 Dec 2020 15:23:59

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:45:57
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'USA-US104-2020-MRNA-1273-P301000024'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:00
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Yes (Y)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:01
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:03
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Yes (Y)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:09
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:11
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:13
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User closed query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 15:19:34
Query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:24:41
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered 'Bruce' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User opened query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 19:04:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Teresa'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered 'Rankin' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Becker'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:32
Un-reviewed for Safety.	System	13 Apr 2021 17:41:46
DataPoint Un-verified.	System	13 Apr 2021 17:41:46
User entered '860 Peachwood Ave'	System	13 Apr 2021 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered '860 Peachwood Dr' reason for change:	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Data Entry Error		
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered '6550 Mapleridge Street'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered 'Deland' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Houston'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 16:24:13

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered '32720' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered '77081'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 13:30:02
User entered 'US'	System	14 Dec 2020 15:23:59

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	13 Apr 2021 17:41:46
User entered '4'	System	01 Mar 2021 17:19:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:19:47
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 18:04:50
User entered '3'	System	22 Feb 2021 18:04:50
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered '2'	System	27 Jan 2021 13:30:11
User entered '1'	System	14 Dec 2020 15:23:59

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:02:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '27/Jan/2021 08:30'	(b) (4) System	27 Jan 2021 13:30:11

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:02:02

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:04:26
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
User entered '1'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 13:30:11

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:45:57
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'USA-US104-2020-MRNA-1273-P301000024'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:00
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Yes (Y)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:01
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:03
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Yes (Y)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:09
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:11
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:13
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User closed query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 15:19:34
Query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:24:41
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered 'Bruce' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User opened query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 19:04:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Teresa'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered 'Rankin' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Becker'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:32
Un-reviewed for Safety.	System	13 Apr 2021 17:41:46
DataPoint Un-verified.	System	13 Apr 2021 17:41:46
User entered '860 Peachwood Ave'	System	13 Apr 2021 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered '860 Peachwood Dr' reason for change:	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Data Entry Error		
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered '6550 Mapleridge Street'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered 'Deland' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Houston'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 16:24:13

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered '32720' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered '77081'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 13:30:02
User entered 'US'	System	14 Dec 2020 15:23:59

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	13 Apr 2021 17:41:46
User entered '4'	System	01 Mar 2021 17:19:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:19:47
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 18:04:50
User entered '3'	System	22 Feb 2021 18:04:50
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered '2'	System	27 Jan 2021 13:30:11
User entered '1'	System	14 Dec 2020 15:23:59

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:02:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:19:47
User entered '22/Feb/2021 12:04'	(b) (4) System	22 Feb 2021 18:04:50

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:02:02

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 17:19:46
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:19:47
User entered '1'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:04:50

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:45:57
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'USA-US104-2020-MRNA-1273-P301000024'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:00
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Yes (Y)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:01
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:03
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Yes (Y)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:09
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:11
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:13
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User closed query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 15:19:34
Query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:24:41
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered 'Bruce' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User opened query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 19:04:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Teresa'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered 'Rankin' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Becker'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:32
Un-reviewed for Safety.	System	13 Apr 2021 17:41:46
DataPoint Un-verified.	System	13 Apr 2021 17:41:46
User entered '860 Peachwood Ave'	System	13 Apr 2021 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered '860 Peachwood Dr' reason for change:	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Data Entry Error		
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered '6550 Mapleridge Street'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered 'Deland' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Houston'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 16:24:13

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered '32720' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered '77081'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 13:30:02
User entered 'US'	System	14 Dec 2020 15:23:59

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	13 Apr 2021 17:41:46
User entered '4'	System	01 Mar 2021 17:19:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:19:47
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 18:04:50
User entered '3'	System	22 Feb 2021 18:04:50
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered '2'	System	27 Jan 2021 13:30:11
User entered '1'	System	14 Dec 2020 15:23:59

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:02:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:31:35
User entered '01/Mar/2021 11:19'	(b) (4) System	01 Mar 2021 17:19:59

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:02:02

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User signature succeeded.	Vicki Miller (b) (4)	02 Mar 2021 21:31:35
User entered 'l'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 17:19:59

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:45:57
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'USA-US104-2020-MRNA-1273-P301000024'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:00
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Yes (Y)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:01
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:03
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:05
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Yes (Y)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:09
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:11
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:46:13
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'No (N)'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User closed query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 15:19:34
Query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 16:24:41
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered 'Bruce' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User opened query 'Site to attempt to update to Investigator/ Address to Dr. Rankin' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 19:04:11
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Teresa'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered 'Rankin' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Becker'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:32
Un-reviewed for Safety.	System	13 Apr 2021 17:41:46
DataPoint Un-verified.	System	13 Apr 2021 17:41:46
User entered '860 Peachwood Ave'	System	13 Apr 2021 17:41:46
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered '860 Peachwood Dr' reason for change:	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Data Entry Error		
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered '6550 Mapleridge Street'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered 'Deland' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered 'Houston'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 16:24:13

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:41:29
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User entered '32720' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 16:24:13
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 15:23:54
User entered '77081'	System	14 Dec 2020 15:23:34

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:19:37
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 13:30:02
User entered 'US'	System	14 Dec 2020 15:23:59

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form

Generated On: 09 Jun 2021 16:02:02

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	13 Apr 2021 17:41:46
User entered '4'	System	01 Mar 2021 17:19:59
User signature succeeded.	Bruce Rankin (b) (4)	22 Feb 2021 18:19:47
	(b) (4)	
Signature has been broken.	System	22 Feb 2021 18:04:50
User entered '3'	System	22 Feb 2021 18:04:50
User signature succeeded.	Bruce Rankin (b) (4)	19 Feb 2021 16:11:03
	(b) (4)	
User entered '2'	System	27 Jan 2021 13:30:11
User entered '1'	System	14 Dec 2020 15:23:59

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:02:02

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:35
User entered '13/Apr/2021 13:41'	System	13 Apr 2021 17:41:46

US3222117

Folder: SAE USA-US104-2020-MRNA-1273-P301000024

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:02:02

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:48:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 16:08:35
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 17:41:46