

US3322006 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:14:11

All time stamps listed in this document are displayed in GMT

US3322006

Form: Participant Creation

Data signed: (b) (4) 26 Feb 2021 01:54:54

Generated On: 11 Aug 2021 22:14:11

[Participant ID](#)

US3322006

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

US3322006

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 14 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) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Date of Birth (MMM yyyy)	(b) (6) 1970
Age	50
Age Units	YEARS
Age (Derived)	50
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
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) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Date of Informed Consent (*dd MMM yyyy*) 14 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1972
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 1972
Start Year (derived)	1972
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Condition	ASTHMA
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 (3)

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Condition	RECURRENT BACK PAIN
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 (4)

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN DEC 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN DEC 2017
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2017
Start Year (derived)	2017
Stop Month and Year (derived)	DEC 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Condition	INTERMITTENT TENSION HEADACHES
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Condition	NUMBNESS/TINGLING OF HANDS/FEET
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 (7)

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Condition	VICODIN ALLERGY
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) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Condition	MIGRAINE HEADACHES
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Start Year (derived)	1986
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Condition	UTERINE MYOMAS
Start date (dd MMM yyyy)	UN JUL 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN DEC 2017
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2017
Start Year (derived)	2017
Stop Month and Year (derived)	DEC 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Condition	HEMORRHOIDS
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: Vital Signs

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:11 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 16:11
Height (<i>xxx.x</i>)	67 in
Weight (<i>xxx.x</i>)	256.6 lb
BMI (<i>xxx.x</i>)	40.27327 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	96.9 F
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>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

14 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: Childbearing Potential

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Date of assessment (*dd MMM yyyy*) 14 AUG 2020

Is the participant of childbearing potential? Yes
No

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) UN DEC 2017

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

PT IS A 50 YEAR OLD AFRICAN AMERICAN FEMALE WITH A BMI >40. PT AND HUSBAND ARE (b) (6) DELIVERY DRIVERS, WHO ARE IN CONTACT WITH APPROX 10 PEOPLE IN THE WAREHOUSE WHILE PICKING UP THE (b) (6)

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
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	True

Specify

PT GOES TO THE STORES AT LEAST ONCE A WEEK AND LIVES IN A HOUSE WITH 3 OTHER PEOPLE. HER DAUGHTER LIVES WITH HER AND WORKS IN AN OFFICE FULL-TIME.

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:55:07

Generated On: 11 Aug 2021 22:14:11

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Feb 2021 01:55:07

Generated On: 11 Aug 2021 22:14:11

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

What was the participant's randomization number? 144024

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

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

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

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

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

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

Liver Disease Yes No

Human Immunodeficiency Virus (HIV) infection Yes No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Feb 2021 01:55:07

Generated On: 11 Aug 2021 22:14:11

Height	67 in
Weight	259.4 lb

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 01:55:07

Generated On: 11 Aug 2021 22:14:11

Height	67 in
Weight	259.4 lb
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>)	17 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:47 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 09:47
Temperature (<i>xxx.x</i>)	96.9 F
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>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 01:55:07

Generated On: 11 Aug 2021 22:14:11

Height	67 in
Weight	259.4 lb
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	12:44 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 12:44
Temperature (xxx.x)	96.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3322006

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 01:55:07

Generated On: 11 Aug 2021 22:14:11

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

17 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 12:06 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 12:06

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) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	17 AUG 2020
Collection time (<i>00:00-23:59</i>)	11:08 (24 HR)
Collection date and time (derived)	17 AUG 2020 11:08

US3322006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Collection date (<i>dd MMM yyyy</i>)			17 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	11:05	17 AUG 2020 11:05
Nasopharyngeal Swab 2	No		

US3322006

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 96.5 °F

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

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

PC Time Stamp 17 AUG 2020 12:46

PC Open Date & Time 17 AUG 2020 12:26

PC Close Date & Time 17 AUG 2020 14:56

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

PC Time Stamp	17 AUG 2020 19:21
PC Open Date & Time	17 AUG 2020 15:51
PC Close Date & Time	18 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:14:11

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	98.1 °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 19:15
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:14:11

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	97.3 °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	19 AUG 2020 19:06
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:14:11

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** 97.3 °F

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

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

PC Time Stamp 20 AUG 2020 19:29

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:14:11

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 <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	21 AUG 2020 20:06
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

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

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

PC Time Stamp 22 AUG 2020 20:29

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:14:11

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	97.7 °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	23 AUG 2020 19:32
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

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	17 AUG 2020 12:48
PC Open Date & Time	17 AUG 2020 12:26
PC Close Date & Time	17 AUG 2020 14:56

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

17 AUG 2020 19:22

PC Open Date & Time

17 AUG 2020 15:51

PC Close Date & Time

18 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:14:11

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

18 AUG 2020 19:15

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:14:11

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

19 AUG 2020 19:07

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:14:11

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

20 AUG 2020 19:26

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:14:11

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

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

21 AUG 2020 20:06

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:14:11

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

22 AUG 2020 20:30

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:14:11

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	23 AUG 2020 19:32
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

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

No

Yes

PC Time stamp	17 AUG 2020 12:49
PC Open Date & Time	17 AUG 2020 12:26
PC Close Date & Time	17 AUG 2020 14:56

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

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

No

Yes

PC Time stamp	17 AUG 2020 19:22
PC Open Date & Time	17 AUG 2020 15:51
PC Close Date & Time	18 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:14:11

	Yes <input type="checkbox"/>
PC Time stamp	18 AUG 2020 19:16
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:14:11

Yes

PC Time stamp	19 AUG 2020 19:07
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:14:11

	Yes <input type="checkbox"/>
PC Time stamp	20 AUG 2020 19:26
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:14:11

Yes

PC Time stamp	21 AUG 2020 20:07
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 6

HEADACHE

- None
- No interference with activity
- Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity
- Any use of prescription pain reliever or prevents daily activity

FATIGUE

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

MUSCLE ACHES ALL OVER BODY

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

JOINT ACHES IN SEVERAL JOINTS

- None
- No interference with activity
- Some interference with activity
- Significant; prevents daily activity

NAUSEA/VOMITING

- None
- No interference with activity or 1-2 episodes/24 hours
- Some interference with activity or >2 episodes/24 hours
- Prevents daily activity, requires outpatient IV hydration

CHILLS

- None
- No interference with activity
- Some interference with activity not requiring medical attention
- Prevents daily activity and requires medical attention

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

No

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:14:11

Yes

PC Time stamp	22 AUG 2020 20:30
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:14:11

	Yes <input type="checkbox"/>
PC Time stamp	23 AUG 2020 19:33
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

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

PC Time Stamp

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

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

PC Time Stamp

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 8

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

ACHES IN SEVERAL JOINTS

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 9

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

ACHES IN SEVERAL JOINTS

None

No interference with activity

Some interference with activity

Significant; prevents daily activity

PC Time stamp

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3322006

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/> Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3322006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3322006

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3322006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3322006

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3322006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 12 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3322006

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3322006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:55:07

Generated On: 11 Aug 2021 22:14:11

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID VISIT2

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 01:55:07

Generated On: 11 Aug 2021 22:14:11

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	_____
Time of assessment (<i>00:00-23:59</i>)	_____
Vital Signs Date and Time (derived)	_____
Temperature (<i>xxx.x</i>)	_____
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	_____
Pulse units	_____
Respiratory Rate (<i>xxx</i>)	_____
Respiratory Rate units	_____
Systolic Blood Pressure (<i>xxx</i>)	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure (<i>xxx</i>)	_____
Diastolic Blood Pressure units	_____

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 01:55:07

Generated On: 11 Aug 2021 22:14:11

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	_____
Time of assessment (<i>00:00-23:59</i>)	_____
Vital Signs Date and Time (derived)	_____
Temperature (<i>xxx.x</i>)	_____
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	_____
Pulse units	_____
Respiratory Rate (<i>xxx</i>)	_____
Respiratory Rate units	_____
Systolic Blood Pressure (<i>xxx</i>)	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure (<i>xxx</i>)	_____
Diastolic Blood Pressure units	_____

US3322006

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 01:55:07

Generated On: 11 Aug 2021 22:14:11

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.

US3322006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 01:55:07

Generated On: 11 Aug 2021 22:14:11

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? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3322006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 01:55:07

Generated On: 11 Aug 2021 22:14:11

Was the sample collected? Yes
No

Collection date (dd MMM yyyy) _____

Collection time (00:00-23:59) _____

Collection date and time (derived) _____

US3322006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 01:55:07

Generated On: 11 Aug 2021 22:14:11

Collection date (*dd MMM yyyy*)

Lab Test

Was the sample collected?

Collection time (*00:00 - 23:59*)

Collection date and time (derived)

Nasopharyngeal Swab 1

Nasopharyngeal Swab 2

US3322006

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:55:07

Generated On: 11 Aug 2021 22:14:11

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3322006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

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 _____

US3322006

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3322006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

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 _____

US3322006

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3322006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

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 _____

US3322006

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3322006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:55:07

Generated On: 11 Aug 2021 22:14:11

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID VISIT3

US3322006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	_____
Time of assessment (<i>00:00-23:59</i>)	_____
Vital Signs Date and Time (derived)	_____
Temperature (<i>xxx.x</i>)	_____
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	_____
Pulse units	_____
Respiratory Rate (<i>xxx</i>)	_____
Respiratory Rate units	_____
Systolic Blood Pressure (<i>xxx</i>)	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure (<i>xxx</i>)	_____
Diastolic Blood Pressure units	_____
Height (derived)	_____
Weight (derived)	_____

US3322006

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:11

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.

US3322006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) _____

Collection time (*00:00-23:59*) _____

Collection date and time (derived) _____

US3322006

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:55:07

Generated On: 11 Aug 2021 22:14:11

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 96

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission	
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Have 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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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 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	02 DEC 2020 13:59:52
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 09:09:50
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 12:30:49
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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 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	24 DEC 2020 07:59:36
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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 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 DEC 2020 05:00:43
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 JAN 2021 07:52:07
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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	13 JAN 2021 08:37:17
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 159

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

No

Yes

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

No

Yes

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

Date and time of submission 20 JAN 2021 03:48:21

Patient Cloud Open Date & Time 20 JAN 2021 00:01

Patient Cloud Close Date & Time 24 JAN 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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 27 JAN 2021 09:28:02

Patient Cloud Open Date & Time 27 JAN 2021 00:01

Patient Cloud Close Date & Time 31 JAN 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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 03 FEB 2021 01:41:35

Patient Cloud Open Date & Time 03 FEB 2021 00:01

Patient Cloud Close Date & Time 07 FEB 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 03:24:23
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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	18 FEB 2021 02:27:46
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 194

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

No
Yes

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

No
Yes

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

Date and time of submission	24 FEB 2021 03:45:22
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAR 2021 03:25:04
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	11 MAR 2021 02:17:27
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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	17 MAR 2021 10:11:23
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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 <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	24 MAR 2021 22:38:24
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 MAR 2021 17:56:28
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 APR 2021 03:03:01
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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	15 APR 2021 15:46:48
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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	21 APR 2021 15:58:03
Patient Cloud Open Date & Time	21 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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 28 APR 2021 04:34:35

Patient Cloud Open Date & Time 28 APR 2021 00:01

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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 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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission	
Patient Cloud Open Date & Time	19 MAY 2021 00:01
Patient Cloud Close Date & Time	23 MAY 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission	
Patient Cloud Open Date & Time	26 MAY 2021 00:01
Patient Cloud Close Date & Time	30 MAY 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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°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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#) 08 AUG 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#) 29 AUG 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

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

[Patient Cloud Close Date & Time](#) 05 SEP 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	12 SEP 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission	
Patient Cloud Open Date & Time	15 SEP 2021 00:01
Patient Cloud Close Date & Time	19 SEP 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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°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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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°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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2021 00:01
Patient Cloud Close Date & Time	24 OCT 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission	
Patient Cloud Open Date & Time	22 DEC 2021 00:01
Patient Cloud Close Date & Time	26 DEC 2021 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

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30 JAN 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	06 FEB 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

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13 FEB 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

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20 FEB 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

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US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

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06 MAR 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

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09 MAR 2022 00:01

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13 MAR 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

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27 MAR 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

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03 APR 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 20 APR 2022 00:01

[Patient Cloud Close Date & Time](#) 24 APR 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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°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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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°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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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°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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	14 AUG 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

Patient Cloud Open Date & Time	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3322006

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:14:11

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		02 MAR 2021 20:12:23

US3322006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

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 _____

US3322006

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3322006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 10 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3322006

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3322006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 12 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3322006

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3322006

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 09 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3322006

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3322006

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 24 MAR 2021

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

Folder OID VISIT4

US3322006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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) _____

US3322006

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

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.

US3322006

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Apr 2021 16:17:57

Generated On: 11 Aug 2021 22:14:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	24 MAR 2021
Collection time (<i>00:00-23:59</i>)	11:52 (24 HR)
Collection date and time (derived)	24 MAR 2021 11:52

US3322006

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3322006

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 16:17:57

Generated On: 11 Aug 2021 22:14:11

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 09 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3322006

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 16:17:57

Generated On: 11 Aug 2021 22:14:11

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3322006

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

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 _____

US3322006

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 26 Feb 2021 01:54:55

Generated On: 11 Aug 2021 22:14:11

Date of Contact	14 SEP 2020
Time of Contact	00:00
Date and Time of Contact (derived)	14 SEP 2020 00:00
Type of Contact	Clinic Visit - Scheduled <input type="radio"/> Clinical Visit - Unscheduled <input checked="" 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"/>

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

Symptom Day

Day 1	<input checked="" 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 type="checkbox"/>
Day 32	<input type="checkbox"/>

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

	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 SEP 2020
------	------------

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

O2 Saturation	<hr/>
---------------	-------

O2 Saturation Units	<hr/>
---------------------	-------

Temperature	<hr/>
-------------	-------

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

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

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

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

Symptom Day

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

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

	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 SEP 2020
------	-------------

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

O2 Saturation	97 %
---------------	------

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 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 14 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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"/>

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

	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 SEP 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 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 14 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

	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 SEP 2020
------	-------------

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

O2 Saturation	92 %
---------------	------

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

Temperature	98.2 F
-------------	--------

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

Cough	None	<input 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 14 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

	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 SEP 2020
------	-------------

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

O2 Saturation	93 %
---------------	------

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

Temperature	98.2 F
-------------	--------

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

Cough	None	<input 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

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

Symptom Day

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

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

	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 SEP 2020

Assessment Not Done False

O2 Saturation 99 %

O2 Saturation Units %

Temperature 97.2 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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"/>

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

	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 SEP 2020
------	-------------

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

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

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 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 14 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

	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 SEP 2020
------	-------------

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

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

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

Temperature	98.2 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

	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 SEP 2020
------	-------------

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

O2 Saturation	97 %
---------------	------

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)

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

	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 SEP 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 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 14 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

	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 SEP 2020
------	-------------

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

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

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

Temperature	97.1 F
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

	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 SEP 2020
------	-------------

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

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

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

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

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

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

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

Assessment Not Done	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 14 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

Date	27 SEP 2020
------	-------------

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

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

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

Temperature	96.9 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 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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Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 31 Mar 2021 23:42:10

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Symptom Day

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

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

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

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

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

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

Temperature	97.3 F
-------------	--------

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

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

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

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

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Form: Symptom Log (15)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

Symptom Day

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

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Form: Symptom Log (16)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

	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 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

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Form: Symptom Log (16)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

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Form: Symptom Log (16)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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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Form: Symptom Log (17)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

	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 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

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Form: Symptom Log (17)

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Not Done

Fatigue None

Mild

Moderate

Severe

Not Done

Muscle Aches (Myalgia) None

Mild

Moderate

Severe

Not Done

Body Aches None

Mild

Moderate

Severe

Not Done

Headache None

Mild

Moderate

Severe

Not Done

New Loss of Taste None

Mild

Moderate

Severe

Not Done

New Loss of Smell None

Mild

Moderate

Severe

Not Done

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

	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 SEP 2020
------	-------------

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

O2 Saturation	<hr/>
---------------	-------

O2 Saturation Units	<hr/>
---------------------	-------

Temperature	<hr/>
-------------	-------

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

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

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

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

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Form: Symptom Log (18)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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 14 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

	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 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

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Form: Symptom Log (19)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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"/>

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

	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 SEP 2020
------	-------------

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

O2 Saturation	ND - Not Done
---------------	---------------

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

Temperature	97.2 F
-------------	--------

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

Cough	None	<input 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

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EAB) (1725)

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Data signed: (b) (4) 31 Mar 2021 23:42:10

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Feb 2021 01:54:55

Generated On: 11 Aug 2021 22:14:11

Date of Visit 14 SEP 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 14 SEP 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

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Apr 2021 16:17:57

Generated On: 11 Aug 2021 22:14:11

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 17 SEP 2020

End Date 18 SEP 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 _____

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Apr 2021 16:17:57

Generated On: 11 Aug 2021 22:14:11

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 _____

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 23 Apr 2021 16:17:57

Generated On: 11 Aug 2021 22:14:11

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 _____

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Feb 2021 01:54:55

Generated On: 11 Aug 2021 22:14:11

[Generate Next COVID-19 Assessment](#)

Yes

No

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	16 SEP 2020
Day 5	Yes	18 SEP 2020
Day 7	Yes	21 SEP 2020
Day 9	Yes	23 SEP 2020
Day 14	Yes	28 SEP 2020
Day 21	Yes	05 OCT 2020
Day 28	Yes	08 OCT 2020

US3322006

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:15 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 14:15
Height (<i>xxx.x</i>)	67 in
Weight (<i>xxx.x</i>)	256.6 lb
Temperature (<i>xxx.x</i>)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	91 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	95 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3322006

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

14 SEP 2020

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

US3322006

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

14 SEP 2020

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:54:55

Generated On: 11 Aug 2021 22:14:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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	SICKD28

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 01:54:55

Generated On: 11 Aug 2021 22:14:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	08 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	13:30 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 13:30
Height (<i>xxx.x</i>)	67 in
Weight (<i>xxx.x</i>)	255 lb
Temperature (<i>xxx.x</i>)	97.9 F
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>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	104 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 01:54:55

Generated On: 11 Aug 2021 22:14:11

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

8 OCT 2020

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

US3322006

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 26 Feb 2021 01:54:55

Generated On: 11 Aug 2021 22:14:11

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

08 OCT 2020

US3322006

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

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 23 JAN 2021

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

Folder OID UNBLND_DECIDE

US3322006

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

Form: Unblinding

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

Date of updated informed consent (<i>dd MMM yyyy</i>)	23 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	23 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3322006

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3322006

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 JAN 2021
Time of assessment (00:00-23:59)	13:11 (24 HR)
Vital Signs Date and Time (derived)	23 JAN 2021 13:11
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3322006

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 JAN 2021
Time of assessment (00:00-23:59)	15:45 (24 HR)
Vital Signs Date and Time (derived)	23 JAN 2021 15:45
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3322006

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

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

23 JAN 2021

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

US3322006

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

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 23 JAN 2021

What was the treatment time? (00:00-23:59) 14:58 (24 HR)

Treatment Date and Time (derived) 23 JAN 2021 14:58

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

US3322006

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 23 JAN 2021

Collection time (*00:00-23:59*) 14:25 (24 HR)

Collection date and time (derived) 23 JAN 2021 14:25

US3322006

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 23 JAN 2021

Collection time (*00:00 - 23:59*) 14:20

Collection Date and Time (derived) 23 JAN 2021 14:20

US3322006

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

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3322006

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 02 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3322006

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:54:57

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 23 FEB 2021

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

Folder OID OLD29

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

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>)	23 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	14:09 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 14:09
Temperature (<i>xxx.x</i>)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	84 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	13 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>)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

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>)	23 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	15:45 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 15:45
Temperature (<i>xxx.x</i>)	96.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	77 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3322006

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

23 FEB 2021

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

US3322006

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 23 FEB 2021

What was the treatment time? (00:00-23:59) 15:09 (24 HR)

Treatment Date and Time (derived) 23 FEB 2021 15:09

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

What was the frequency of the study treatment dosing? ONCE

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

US3322006

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3322006

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 03 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3322006

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3322006

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 24 MAR 2021

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

Folder OID OLD57

US3322006

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

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) _____

US3322006

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

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.

US3322006

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	24 MAR 2021
Collection time (<i>00:00-23:59</i>)	11:52 (24 HR)
Collection date and time (derived)	24 MAR 2021 11:52

US3322006

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Feb 2021 01:54:54

Generated On: 11 Aug 2021 22:14:11

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 19:24:34

Generated On: 11 Aug 2021 22:14:11

AEID USA-US060-2020-MRNA-1273-P30
1000003

Adverse event SYMPTOMATIC 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) 09 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 20 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild
Grade 2/Moderate
Grade 3/Severe
Grade 4

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 19:24:34

Generated On: 11 Aug 2021 22:14:11

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 <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 19:24:34

Generated On: 11 Aug 2021 22:14:11

AEID	
Adverse event	HEMATOCHEZIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	28 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 19:24:34

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Apr 2021 19:24:34

Generated On: 11 Aug 2021 22:14:11

AEID	
Adverse event	HYPERTENSION
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	08 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Apr 2021 19:24:34

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Feb 2021 01:54:55

Generated On: 11 Aug 2021 22:14:11

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

Yes

No

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

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

Name of Medication ALBUTEROL SULFATE

Prophylaxis Yes
No

Indication ASTHMA

Dose per administration 90

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

Intramuscular	<input type="radio"/>
Respiratory (Inhalation)	<input checked="" type="radio"/>
Intralesional	<input type="radio"/>
Intraperitoneal	<input type="radio"/>
Nasal	<input type="radio"/>
Vaginal	<input type="radio"/>
Rectal	<input type="radio"/>
Intravenous	<input type="radio"/>
Intravenous Bolus	<input type="radio"/>
Intravenous Drip	<input type="radio"/>
Other	<input type="radio"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) UN UNK 2012

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
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

Name of Medication ASPIRIN (NSAID*)
845MG/CAFFEINE 65 MG(BC
POWDER)

Prophylaxis Yes
No

Indication INTERMITTENT TENSION
HEADACHES

Dose per administration 845/65

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 24 Mar 2021 21:49:40

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- 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) UN JAN 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

Name of Medication ASPIRIN (NSAID*)
845MG/CAFFEINE 65 MG(BC
POWDER)

Prophylaxis Yes
No

Indication MIGRAINE HEADACHES

Dose per administration 845/65

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

	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 2019

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

Name of Medication ASPIRIN (NSAID*) 845
MG/CAFFEINE 65 MG(BC
POWDER)

Prophylaxis Yes
No

Indication HEADACHE

Dose per administration 845/65

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

	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) 22 AUG 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 23 AUG 2020

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

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

Name of Medication LORATADINE (CLARITIN)

Prophylaxis Yes
No

Indication SEASONAL ALLERGIES

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 28 SEP 2020

Start date completely unknown False

Ongoing? Yes
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

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

Name of Medication ANTIHISTAMINE EYE DROPS
[UNKNOWN]

Prophylaxis Yes
No

Indication SEASONAL ALLERGIES

Dose per administration 2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify DROPS

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 28 SEP 2020

Start date completely unknown False

Ongoing? Yes
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

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

Name of Medication NYQUIL [ACETAMINOPHEN,
DEXTROMETHORPHAN
HYDROBROMIDE,
DOXYLAMINE SUCCINATE
PHENYLEPHRINE
HYDROCHLORIDE]

Prophylaxis Yes
No

Indication SYMPTOMATIC COVID-19

Dose per administration 650/20/12.5/10

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

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

	Topical	<input type="checkbox"/>
	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	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) 09 SEP 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 18 SEP 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

Name of Medication ASPIRIN/CAFFEINE

Prophylaxis Yes
No

Indication HEADACHE

Dose per administration 845/65

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 (9)

Data signed: (b) (4) 24 Mar 2021 21:49:40

Generated On: 11 Aug 2021 22:14:11

	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*) 06 FEB 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 06 FEB 2021

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

US3322006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Feb 2021 01:54:55

Generated On: 11 Aug 2021 22:14:11

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3322006

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

Date of dosing discontinuation (dd MMM yyyy) 9 SEP 2020

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 _____

US3322006

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:14:11

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

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

SAEID	USA-US060-2020-MRNA-1273-P30 1000003
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	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

SAEID	USA-US060-2020-MRNA-1273-P30 1000003
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	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/SEP/2020 14:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

SAEID USA-US060-2020-MRNA-1273-P30
1000003

Serious Yes
No

Death Yes
No

Life threatening Yes
No

Requires inpatient or prolongation of existing Hospitalization Yes
No

Persistent or significant disability or incapacity Yes
No

Congenital anomaly or birth defect Yes
No

Other medically important event Yes
No

Investigator's First Name VERONICA

Investigator's Last Name FRAGOSO

Site Address: Street 6550 MAPLERIDGE STREET

Site Address: City HOUSTON

Site Address: State TX

Site Address: Postal Code 77081

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 3

Date of submission (Pre-filled from custom function) 29/SEP/2020 12:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. True

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

SAEID	USA-US060-2020-MRNA-1273-P30 1000003
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	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	07/OCT/2020 13:25
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

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Feb 2021 01:54:56

Generated On: 11 Aug 2021 22:14:11

SAEID USA-US060-2020-MRNA-1273-P30
1000003

Serious Yes
No

Death Yes
No

Life threatening Yes
No

Requires inpatient or prolongation of existing Hospitalization Yes
No

Persistent or significant disability or incapacity Yes
No

Congenital anomaly or birth defect Yes
No

Other medically important event Yes
No

Investigator's First Name VERONICA

Investigator's Last Name FRAGOSO

Site Address: Street 6550 MAPLERIDGE STREET

Site Address: City HOUSTON

Site Address: State TX

Site Address: Postal Code 77081

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 3

Date of submission (Pre-filled from custom function)

**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

US3322006 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

US3322006

Form: Participant Creation

Generated On: 11 Aug 2021 22:14:11

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'US3322006'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 22:34:15

US3322006

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:41:28

US3322006

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '14 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 22:34:16

US3322006

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[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 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Clinic (Clinic)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:41:28

US3322006

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'SCRN'	System	14 Aug 2020 22:41:28

US3322006

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:11

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered (b) (6) 1970'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 22:34:17

US3322006

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:11

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '50'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:11

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'YEARS'	System	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered '50'	System	14 Aug 2020 22:42:04

US3322006

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:11

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Female (F)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:11

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Frances Saubon (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:11

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	Frances Saubon (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:11

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '1'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:11

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	Frances Saubon (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	Frances Saubon (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	Frances Saubon (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:11

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:11

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	Frances Saubon (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:14:11

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	Frances Saubon (b) (4)	14 Aug 2020 22:41:49

US3322006

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:14:11

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '14 Aug 2020'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:42:04

US3322006

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'Aug 2020'	System	14 Aug 2020 22:42:04

US3322006

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered '2020'	System	14 Aug 2020 22:42:04

US3322006

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:14:11

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Amendment 2 (2)'	Frances Saubon (b) (4)	14 Aug 2020 22:42:04

US3322006

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:42:04

US3322006

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:14:11

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:42:04

US3322006

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:14:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:42:04

US3322006

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:14:11

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	Frances Saubon (b) (4)	14 Aug 2020 22:42:04

US3322006

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:14:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	14 Aug 2020 22:34:16

US3322006

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:14:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered '1'	System	14 Aug 2020 22:42:08

US3322006

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:42:08

US3322006

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:14:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:42:22

US3322006

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:14:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
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)	15 Aug 2020 00:22:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:22:41
Data point term sent to Coder	System	14 Aug 2020 22:44:04
User entered 'Seasonal Allergies'	Frances Saubon (b) (4)	14 Aug 2020 22:43:08

US3322006

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'UN UNK 1972'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:43:08

US3322006

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:14:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:43:08

US3322006

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:14:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:43:08

US3322006

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:43:08

US3322006

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:14:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:43:08

US3322006

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:14:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'Jan 1972'	System	14 Aug 2020 22:43:08

US3322006

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:14:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered '1972'	System	14 Aug 2020 22:43:08

US3322006

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	14 Aug 2020 22:43:08

US3322006

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	14 Aug 2020 22:43:08

US3322006

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:14:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:28:52
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Concomitant medication page is updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:25:23
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 06:43:59
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:16
Data point term sent to Coder System	System	14 Aug 2020 22:44:04
User entered 'Asthma'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:43:36

US3322006

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'UN UNK 2012'	Frances Saubon (b) (4)	14 Aug 2020 22:43:36

US3322006

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:14:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:43:36

US3322006

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:14:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:43:36

US3322006

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:43:36

US3322006

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:14:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	Frances Saubon (b) (4)	14 Aug 2020 22:43:36

US3322006

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:14:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'Jan 2012'	System	14 Aug 2020 22:43:36

US3322006

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:14:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered '2012'	System	14 Aug 2020 22:43:36

US3322006

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	14 Aug 2020 22:43:36

US3322006

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	14 Aug 2020 22:43:36

US3322006

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:14:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 00:22:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 00:22:16
Data point term sent to Coder	System	14 Aug 2020 22:44:06
User entered 'Recurrent Back Pain'	Frances Saubon (b) (4)	14 Aug 2020 22:43:51

US3322006

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'UN UNK 2015'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:43:51

US3322006

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:14:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	Frances Saubon (b) (4)	14 Aug 2020 22:43:51

US3322006

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:14:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:43:51

US3322006

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:43:51

US3322006

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:14:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	Frances Saubon (b) (4)	14 Aug 2020 22:43:51

US3322006

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:14:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'Jan 2015'	System	14 Aug 2020 22:43:51

US3322006

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:14:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered '2015'	System	14 Aug 2020 22:43:51

US3322006

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	14 Aug 2020 22:43:51

US3322006

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	14 Aug 2020 22:43:51

US3322006

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:14:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per DM CLR: Please note that a surgical procedure of hysterectomy was performed = UN DEC 2017. However, the reason provided in the childbearing potential ecrf is OTHER and the date of surgical sterilization was not indicated. Please review and update if appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:29:52
Query 'Per DM CLR: Please note that a surgical procedure of hysterectomy was performed = UN DEC 2017. However, the reason provided in the childbearing potential ecrf is OTHER and the date of surgical sterilization was not indicated. Please review and update if appropriate. Otherwise, clarify. ' answered with 'Data updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:16:56
User opened query 'Per DM CLR: Please note that a surgical procedure of hysterectomy was performed = UN DEC 2017. However, the reason provided in the childbearing potential ecrf is OTHER and the date of surgical sterilization was not indicated. Please review and update if appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 06:44:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:22:16
Data point term sent to Coder	System	14 Aug 2020 22:45:06
User entered 'Hysterectomy'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:44:26

US3322006

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'UN Dec 2017'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:44:26

US3322006

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:14:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:44:26

US3322006

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:14:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:44:26

US3322006

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'UN Dec 2017'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:44:26

US3322006

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:14:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:44:26

US3322006

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:14:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'Dec 2017'	System	14 Aug 2020 22:44:26

US3322006

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:14:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered '2017'	System	14 Aug 2020 22:44:26

US3322006

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'Dec 2017'	System	14 Aug 2020 22:44:26

US3322006

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered '2017'	System	14 Aug 2020 22:44:26

US3322006

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:14:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Tension headache, LLT: Tension headaches - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 07:27:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 07:27:07
Data point term sent to Coder	System	14 Aug 2020 22:45:06
User entered 'Intermittent Tension Headaches'	Frances Saubon (b) (4)	14 Aug 2020 22:44:50

US3322006

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:14:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'UN UNK 1980'	Frances Saubon (b) (4)	14 Aug 2020 22:44:50

US3322006

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:14:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:44:50

US3322006

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:14:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:44:50

US3322006

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:44:50

US3322006

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:14:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	Frances Saubon (b) (4)	14 Aug 2020 22:44:50

US3322006

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:14:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'Jan 1980'	System	14 Aug 2020 22:44:50

US3322006

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:14:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered '1980'	System	14 Aug 2020 22:44:50

US3322006

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	14 Aug 2020 22:44:50

US3322006

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	14 Aug 2020 22:44:50

US3322006

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:14:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Paraesthesia, LLT: Tingling feet/hands - version MedDRA\23.0.	Coder Import (b) (4)	25 Nov 2020 00:43:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	25 Nov 2020 00:43:12
Data point term sent to Coder	System	14 Aug 2020 22:46:07
User entered 'Numbness/Tingling of Hands/Feet'	Frances Saubon (b) (4)	14 Aug 2020 22:45:10

US3322006

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'UN UNK 2015'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:45:10

US3322006

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:14:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:45:10

US3322006

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:14:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:45:10

US3322006

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:45:10

US3322006

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:14:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:45:10

US3322006

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:14:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'Jan 2015'	System	14 Aug 2020 22:45:10

US3322006

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:14:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered '2015'	System	14 Aug 2020 22:45:10

US3322006

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	14 Aug 2020 22:45:10

US3322006

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	14 Aug 2020 22:45:10

US3322006

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:14:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 15:43:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 15:43:49
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:22:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:22:19
Data point term sent to Coder	System	14 Aug 2020 22:46:07
User entered 'Vicodin Allergy'	Frances Saubon (b) (4)	14 Aug 2020 22:45:33
	(b) (4)	

US3322006

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'UN UNK 2015'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:45:33

US3322006

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:14:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:45:33

US3322006

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:14:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:45:33

US3322006

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:45:33

US3322006

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:14:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:45:33

US3322006

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:14:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'Jan 2015'	System	14 Aug 2020 22:45:33

US3322006

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:14:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered '2015'	System	14 Aug 2020 22:45:33

US3322006

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	14 Aug 2020 22:45:33

US3322006

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	14 Aug 2020 22:45:33

US3322006

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:14:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User coded data point as SOC: Nervous system disorders, HLGHT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:22:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 00:22:20
Data point term sent to Coder	System	14 Aug 2020 22:46:07
User entered 'Migraine Headaches'	Frances Saubon (b) (4)	14 Aug 2020 22:45:50

US3322006

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:14:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'UN UNK 1986'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:45:50

US3322006

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:14:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:45:50

US3322006

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:14:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:45:50

US3322006

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:45:50

US3322006

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:14:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:45:50

US3322006

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:14:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'Jan 1986'	System	14 Aug 2020 22:45:50

US3322006

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:14:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered '1986'	System	14 Aug 2020 22:45:50

US3322006

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	14 Aug 2020 22:45:50

US3322006

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	14 Aug 2020 22:45:50

US3322006

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:14:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine myoma - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 05:59:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 05:59:39
Data point term sent to Coder	System	14 Aug 2020 22:47:08
User entered 'Uterine Myomas'	Frances Saubon (b) (4)	14 Aug 2020 22:46:12

US3322006

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'UN Jul 2017'	Frances Saubon (b) (4)	14 Aug 2020 22:46:12

US3322006

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:14:11

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:46:12

US3322006

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:14:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:46:12

US3322006

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'UN Dec 2017' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 22:04:47
User entered 'UN Jul 2017'	Frances Saubon (b) (4)	14 Aug 2020 22:46:12
	(b) (4)	

US3322006

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:14:11

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per DM CLR: Please note, Stop date of MH = UN July 2017. However, Hysterectomy's start/stop date recorded is UN DEC 2017 which is unexpected. Review and reconcile dates as appropriate. Else, clarify. (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 18:30:45
Query 'Per DM CLR: Please note, Stop date of MH = Frances Saubon UN July 2017. However, Hysterectomy's start/stop date recorded is UN DEC 2017 which is unexpected. Review and reconcile dates as appropriate. Else, clarify. answered with 'Data updated per query resolution. Thank you' (Site from DM).	(b) (4) (b) (4)	22 Sep 2020 22:05:14
User opened query 'Per DM CLR: Please note, Stop date of MH = UN July 2017. However, Hysterectomy's start/stop date recorded is UN DEC 2017 which is unexpected. Review and reconcile dates as appropriate. Else, clarify. (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 06:45:57
User entered '0'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:46:12

US3322006

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:14:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'Jul 2017'	System	14 Aug 2020 22:46:12

US3322006

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:14:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered '2017'	System	14 Aug 2020 22:46:12

US3322006

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'Dec 2017'	System	22 Sep 2020 22:04:47
User entered 'Jul 2017'	System	14 Aug 2020 22:46:12

US3322006

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered '2017'	System	14 Aug 2020 22:46:12

US3322006

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:14:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Hemorrhoids - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:36:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:36:48
Data point term sent to Coder	System	16 Nov 2020 20:36:20
User entered 'Hemorrhoids'	Frances Saubon (b) (4)	16 Nov 2020 20:35:45

US3322006

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'UN UNK 2010'	(b) (4) Frances Saubon (b) (4)	16 Nov 2020 20:35:45

US3322006

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:14:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	16 Nov 2020 20:35:45

US3322006

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:14:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	16 Nov 2020 20:35:45

US3322006

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Frances Saubon (b) (4)	16 Nov 2020 20:35:45

US3322006

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:14:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	16 Nov 2020 20:35:45

US3322006

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:14:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'Jan 2010'	System	16 Nov 2020 20:35:45

US3322006

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:14:11

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered '2010'	System	16 Nov 2020 20:35:45

US3322006

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	16 Nov 2020 20:35:45

US3322006

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	16 Nov 2020 20:35:45

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Frances Saubon (b) (4)	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '14 Aug 2020'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '16:11'	Frances Saubon (b) (4)	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered '14 Aug 2020 16:11'	System	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '67' in	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:47:36
DataPoint set to visible.	(b) (4) System	14 Aug 2020 22:42:08

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '256.6' lb	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:47:36
DataPoint set to visible.	(b) (4) System	14 Aug 2020 22:42:08

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
Amendment Manager: User entered '40.27327'	System	16 Sep 2020 23:58:15
User entered '40.3'	System	14 Aug 2020 22:47:36
DataPoint set to visible.	System	14 Aug 2020 22:42:08

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'kg/m2'	System	14 Aug 2020 22:47:36
DataPoint set to visible.	System	14 Aug 2020 22:42:08

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '96.9' F	Frances Saubon (b) (4)	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Oral (Oral)'	Frances Saubon (b) (4)	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '75'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'bpm'	System	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '18'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'breaths/min'	System	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '134'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'mmHg'	System	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '84'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'mmHg'	System	14 Aug 2020 22:47:36

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11

US3322006

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11

US3322006

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:11

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Frances Saubon (b) (4)	14 Aug 2020 22:47:43

US3322006

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
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)	27 Aug 2020 12:58:15
Comment added 'Screening visit was conducted 14-Aug-2020 and Physical exam was also conducted 14-Aug-2020'.	Elisa Moralez (b) (4) (b) (4)	18 Aug 2020 14:59:48
Comment added 'visit date and physical examination date are identical'.	Elisa Moralez (b) (4) (b) (4)	17 Aug 2020 20:53:23
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	17 Aug 2020 19:13:50
User entered '14 Aug 2020'	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:47:43

US3322006

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:14:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '14 Aug 2020'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:48:37

US3322006

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:48:37

US3322006

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:14:11

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	(b) (4)	
User closed query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	Frances Saubon (b) (4)	22 Sep 2020 20:16:10
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Is the participant of childbearing potential is No, however reason is missing. Please provide.' (Site from System).	System	14 Aug 2020 22:50:44
User entered empty.	Frances Saubon (b) (4)	14 Aug 2020 22:50:44
	(b) (4)	
	System	14 Aug 2020 22:48:37
	Frances Saubon (b) (4)	14 Aug 2020 22:48:37
	(b) (4)	

US3322006

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:14:11

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty; reason for change Data Entry Error	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:16:10
User entered 'Hysterectomized'	Frances Saubon (b) (4)	14 Aug 2020 22:48:37
	(b) (4)	

US3322006

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 01:54:59
User entered 'UN Dec 2017' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:16:10
User entered empty.	Frances Saubon (b) (4) (b) (4)	14 Aug 2020 22:48:37

US3322006

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:14:11

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:48:37

US3322006

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:48:37

US3322006

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:14:11

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:48:37

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

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 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

[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 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

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 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

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 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

[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 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

[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 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

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 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

[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 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

[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 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

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 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

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 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Pt is a 50 year old African American female with a BMI >40. PT and husband are (b) (6) delivery drivers, who are in contact with approx 10 people in the warehouse while picking up the (b) (6)'	Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

[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 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

[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 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

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 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '1'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '1'	(b) (4) Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:14:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Pt goes to the stores at least once a week and lives in a house with 3 other people. Her daughter lives with her and works in an office full-time.'	Frances Saubon (b) (4)	14 Aug 2020 22:50:27

US3322006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User closed query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "Sample is collecte on 08-Oct-2020 for Illness Visit Day 28", & per PPD portal, swab sample for 08-OCT-2020 is reported under Unscheduled visit; however, corresponding swab sample is missing in EDC. Kindly consider initiating Covid -19 assessment eCRF for corresponding date & record swab sample if collected on 08-OCT-2020 for illness visit, also clarify in site response correct visit for which swab sample was collected.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 07:29:56
Query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "Sample is collected on 08-Oct-2020 for Illness Visit Day 28", & per PPD portal, swab sample for 08-OCT-2020 is reported under Unscheduled visit; however, corresponding swab sample is missing in EDC. Kindly consider initiating Covid -19 assessment eCRF for corresponding date & record swab sample if collected on 08-OCT-2020 for illness visit, also clarify in site response correct visit for which swab sample was collected.' answered with 'Assessment filled out per request, nasal swab logged for day 28 convalescence visit, but please consider inactivating Symptom log page under 8-Oct-2020 Covid assessment, as it would be repetitive to enter the same data from the original visit. ' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 22:46:46
User opened query 'Per GCL Lab Reconciliation requery: Swab: Per site response, "Sample is collecte on 08-Oct-2020 for Illness Visit Day 28", & per PPD portal, swab sample for 08-OCT-2020 is reported under Unscheduled visit; however, corresponding swab sample is missing in EDC. Kindly consider initiating Covid -19 assessment eCRF for corresponding date & record swab sample if collected on 08-OCT-2020 for illness visit, also clarify in site response correct visit for which swab sample was collected.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 06:12:51

US3322006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 08OCT2020 is reported underUnscheduled 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)	03 Nov 2020 11:43:04
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 08OCT2020 is reported underUnscheduled in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Sample is collected on 08-Oct-2020 for Illness Visit Day 28. A DCF has been submitted to reflect changes.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	30 Oct 2020 14:52:07
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 08OCT2020 is reported underUnscheduled 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)	30 Oct 2020 06:11:07
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:13:50

US3322006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered '17 Aug 2020'	Frances Saubon (b) (4)	17 Aug 2020 19:13:50

US3322006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered 'Clinic (Clinic)'	Frances Saubon (b) (4)	17 Aug 2020 19:13:50

US3322006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered 'VISIT1'	System	17 Aug 2020 19:13:50

US3322006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 15:59:51

US3322006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:44:58
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:44:58
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 15:59:51
User entered '144024' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 15:59:51

US3322006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 15:59:51

US3322006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:14:11

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered 'No (N)'	Frances Saubon (b) (4)	17 Aug 2020 19:14:13

US3322006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:14:11

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered 'No (N)'	Frances Saubon (b) (4)	17 Aug 2020 19:14:13

US3322006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered 'Yes (Y)'	Frances Saubon (b) (4)	17 Aug 2020 19:14:13

US3322006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:14:11

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered 'No (N)'	Frances Saubon (b) (4)	17 Aug 2020 19:14:13

US3322006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:14:11

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	17 Aug 2020 19:14:13

US3322006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered 'No (N)'	Frances Saubon (b) (4)	22 Sep 2020 22:04:13
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:21:42
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:26:22

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:50:41
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' answered with 'Per source, Screening visit and V1 visit were on 14-Aug-2020 and 17-Aug-2020, respectively.' (Site from DM).	Blessing Felix-Okoroji (b) (4)	09 Nov 2020 20:00:48
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:21:07
User entered '67' in reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	18 Aug 2020 15:49:33
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered '259.4' lb reason for change: Data Entry Error	(b) (4) Frances Saubon (b) (4)	18 Aug 2020 15:49:33
User entered missing code ND - Not Done.	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:50:41
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' answered with 'Per source, Screening visit and V1 visit were on 14-Aug-2020 and 17-Aug-2020, respectively.' (Site from DM).	Blessing Felix-Okoroji (b) (4)	09 Nov 2020 20:00:48
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:21:07
User entered '67' in reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	18 Aug 2020 15:49:33
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered '259.4' lb reason for change: Data Entry Error	(b) (4) Frances Saubon (b) (4)	18 Aug 2020 15:49:33
User entered missing code ND - Not Done.	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User accepted default value 'Pre-Dose (PREDOSE)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered 'Yes (Y)'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	17 Aug 2020 19:24:19
User entered '17 Aug 2020' reason for change: Data Entry Error	Frances Saubon (b) (4)	17 Aug 2020 19:24:19
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Aug 2020 19:18:56
User entered '14 Aug 2020'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered '09:47' reason for change: Data Entry Error	(b) (4)	17 Aug 2020 19:24:19
User entered '16:11'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56
	(b) (4)	

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered '17 Aug 2020 09:47'	System	17 Aug 2020 19:24:19
User entered '14 Aug 2020 16:11'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered '96.9' F	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered 'Oral (Oral)'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered '70' reason for change: Data Entry Error	(b) (4) Frances Saubon (b) (4)	17 Aug 2020 19:24:19
User entered '75'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered 'bpm'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered '16' reason for change: Data Entry Error	(b) (4) Frances Saubon (b) (4)	17 Aug 2020 19:24:19
User entered '18'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered 'breaths/min'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered '134'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered 'mmHg'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered '80' reason for change: Data Entry Error	(b) (4)	
	Frances Saubon (b) (4)	17 Aug 2020 19:24:19
User entered '84'	(b) (4)	
	Frances Saubon (b) (4)	17 Aug 2020 19:18:56
	(b) (4)	

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered 'mmHg'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User closed query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 16:50:41
Query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' answered with 'Per source, Screening visit and V1 visit were on 14-Aug-2020 and 17-Aug-2020, respectively.' (Site from DM).	Blessing Felix-Okoroji (b) (4)	09 Nov 2020 20:00:48
User opened query 'Per CDM: Patient noted as screened and dosed same day. Per CCG, "ND" should be recorded at height and weight. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:21:07
User entered '67' in reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	18 Aug 2020 15:49:33
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered '259.4' lb reason for change: Data Entry Error	(b) (4) Frances Saubon (b) (4)	18 Aug 2020 15:49:33
User entered missing code ND - Not Done.	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User accepted default value 'Post-Dose (POSTDOSE)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered 'Yes (Y)'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered '17 Aug 2020'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 17:50:16
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per source' (Site from System).	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:46:00
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 19:18:56
User entered '12:44'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered '17 Aug 2020 12:44'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 05:58:05
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Frances Saubon (b) (4) (b) (4)	17 Sep 2020 13:18:28
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:58:15
User entered '96.5' F	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered 'Oral (Oral)'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered '66'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered 'bpm'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered '18'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered 'breaths/min'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered '147'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered 'mmHg'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered '87'	Frances Saubon (b) (4)	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered 'mmHg'	System	17 Aug 2020 19:18:56

US3322006

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered 'Yes (Y)'	Frances Saubon (b) (4)	17 Aug 2020 19:25:33

US3322006

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered '17 Aug 2020'	Frances Saubon (b) (4)	17 Aug 2020 19:25:33

US3322006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	17 Aug 2020 17:08:45

US3322006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	17 Aug 2020 17:08:45

US3322006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	17 Aug 2020 17:08:45

US3322006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 17:08:45

US3322006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '17 Aug 2020'	Elisa Moralez (b) (4)	17 Aug 2020 17:08:45

US3322006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '12:06'	Elisa Moralez (b) (4)	17 Aug 2020 17:08:45

US3322006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered '17 Aug 2020 12:06'	System	17 Aug 2020 17:08:45

US3322006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Left Arm (LEFT ARM)'	Elisa Moralez (b) (4)	17 Aug 2020 17:08:45

US3322006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered 'ONCE'	System	17 Aug 2020 17:08:45

US3322006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 17:08:45

US3322006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Frances Saubon (b) (4)	17 Aug 2020 19:25:58

US3322006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '17 Aug 2020'	Frances Saubon (b) (4)	17 Aug 2020 19:25:58

US3322006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '11:08'	Frances Saubon (b) (4)	17 Aug 2020 19:25:58

US3322006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered '17 Aug 2020 11:08'	System	17 Aug 2020 19:25:58

US3322006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:14:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '17 Aug 2020'	(b) (4) Frances Saubon (b) (4)	17 Aug 2020 19:26:26

US3322006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:14:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:26:26

US3322006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:14:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	17 Aug 2020 19:26:26

US3322006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:14:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '11:05'	(b) (4) Frances Saubon (b) (4)	17 Aug 2020 19:26:26

US3322006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:14:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered '17 Aug 2020 11:05'	System	17 Aug 2020 19:26:26

US3322006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:14:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:26:26

US3322006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:14:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	Frances Saubon (b) (4)	17 Aug 2020 19:26:26

US3322006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:14:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Frances Saubon (b) (4)	17 Aug 2020 19:26:26

US3322006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:14:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered empty.	System	17 Aug 2020 19:26:26

US3322006

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Frances Saubon (b) (4)	17 Aug 2020 19:26:31

US3322006

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered '1'	System	17 Aug 2020 19:26:31

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:46:31', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '20859a36-5f35-4635-ab74-589917c94c60'	System	17 Aug 2020 17:46:55
User entered 'Yes (Y)'	System	17 Aug 2020 17:46:55

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:46:36', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '20859a36-5f35-4635-ab74-589917c94c60'	System	17 Aug 2020 17:46:55
User entered '96.5'	System	17 Aug 2020 17:46:55

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:46:40', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '20859a36-5f35-4635-ab74-589917c94c60'	System	17 Aug 2020 17:46:55
User entered 'No (N)'	System	17 Aug 2020 17:46:55

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:46:52', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '20859a36-5f35-4635-ab74-589917c94c60'	System	17 Aug 2020 17:46:55
User entered '17 Aug 2020 12:46'	System	17 Aug 2020 17:46:55

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '17 Aug 2020 12:26'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '17 Aug 2020 14:56'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:21:40', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '142f512d-2d35-47c4-9f0b-7474a9b6ac01'	System	18 Aug 2020 00:21:53
User entered 'Yes (Y)'	System	18 Aug 2020 00:21:53

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:21:44', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '142f512d-2d35-47c4-9f0b-7474a9b6ac01' User entered '98.2'	System	18 Aug 2020 00:21:53
	System	18 Aug 2020 00:21:53

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:21:46', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '142f512d-2d35-47c4-9f0b-7474a9b6ac01'	System	18 Aug 2020 00:21:53
User entered 'No (N)'	System	18 Aug 2020 00:21:53

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:21:51', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '142f512d-2d35-47c4-9f0b-7474a9b6ac01'	System	18 Aug 2020 00:21:53
User entered '17 Aug 2020 19:21'	System	18 Aug 2020 00:21:53

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '17 Aug 2020 15:51'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 2'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:14:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:14:55', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'f15f7a72-bac4-4535-96a9-4dbb1b1b8c31'	System	19 Aug 2020 00:15:21
User entered 'Yes (Y)'	System	19 Aug 2020 00:15:21

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:14:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:15:08', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'f15f7a72-bac4-4535-96a9-4dbb1b1b8c31'	System	19 Aug 2020 00:15:21
User entered '98.1'	System	19 Aug 2020 00:15:21

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:15:11', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'f15f7a72-bac4-4535-96a9-4dbb1b1b8c31'	System	19 Aug 2020 00:15:21
User entered 'No (N)'	System	19 Aug 2020 00:15:21

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:14:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:15:17', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'f15f7a72-bac4-4535-96a9-4dbb1b1b8c31'	System	19 Aug 2020 00:15:21
User entered '18 Aug 2020 19:15'	System	19 Aug 2020 00:15:21

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 3'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:14:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:06:34', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'ad6786c4-ef2e-4853-a6c6-68ba1838a6dc'	System	20 Aug 2020 00:06:47
User entered 'Yes (Y)'	System	20 Aug 2020 00:06:47

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:14:11

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:06:39', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'ad6786c4-ef2e-4853-a6c6-68ba1838a6dc'	System	20 Aug 2020 00:06:47
User entered '97.3'	System	20 Aug 2020 00:06:47

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:06:41', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'ad6786c4-ef2e-4853-a6c6-68ba1838a6dc'	System	20 Aug 2020 00:06:47
User entered 'No (N)'	System	20 Aug 2020 00:06:47

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:14:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:06:44', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'ad6786c4-ef2e-4853-a6c6-68ba1838a6dc'	System	20 Aug 2020 00:06:47
User entered '19 Aug 2020 19:06'	System	20 Aug 2020 00:06:47

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 4'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:14:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:29:30', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'e00b167e-12f1-42dd-a1a8-4935afe3c9e7'	System	21 Aug 2020 00:29:40
User entered 'Yes (Y)'	System	21 Aug 2020 00:29:40

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:14:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:29:34', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'e00b167e-12f1-42dd-a1a8-4935afe3c9e7'	System	21 Aug 2020 00:29:40
User entered '97.3'	System	21 Aug 2020 00:29:40

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:29:37', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'e00b167e-12f1-42dd-a1a8-4935afe3c9e7'	System	21 Aug 2020 00:29:40
User entered 'No (N)'	System	21 Aug 2020 00:29:40

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:14:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:29:39', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'e00b167e-12f1-42dd-a1a8-4935afe3c9e7'	System	21 Aug 2020 00:29:40
User entered '20 Aug 2020 19:29'	System	21 Aug 2020 00:29:40

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 5'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:14:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:06:03', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'f732705e-fbb1-42b3-bcae-01b1fa63a06c'	System	22 Aug 2020 01:06:23
User entered 'Yes (Y)'	System	22 Aug 2020 01:06:23

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:14:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:06:09', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'f732705e-fbb1-42b3-bcae-01b1fa63a06c'	System	22 Aug 2020 01:06:23
User entered '97.8'	System	22 Aug 2020 01:06:23

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:06:14', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'f732705e-fbb1-42b3-bcae-01b1fa63a06c'	System	22 Aug 2020 01:06:23
User entered 'No (N)'	System	22 Aug 2020 01:06:23

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:14:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:06:18', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'f732705e-fbb1-42b3-bcae-01b1fa63a06c'	System	22 Aug 2020 01:06:23
User entered '21 Aug 2020 20:06'	System	22 Aug 2020 01:06:23

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 6'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:14:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:29:37', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4e21ae2c-628b-4813-aba6-d5092674fa55'	System	23 Aug 2020 01:29:58
User entered 'Yes (Y)'	System	23 Aug 2020 01:29:58

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:14:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:29:41', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4e21ae2c-628b-4813-aba6-d5092674fa55'	System	23 Aug 2020 01:29:58
User entered '97.6'	System	23 Aug 2020 01:29:58

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:29:46', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4e21ae2c-628b-4813-aba6-d5092674fa55'	System	23 Aug 2020 01:29:58
User entered 'Yes (Y)'	System	23 Aug 2020 01:29:58

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'follow-up call revealed patient took aspirin for headache' (Site from System).	(b) (4)	25 Aug 2020 12:52:18
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Elisa Moralez (b) (4) (b) (4)	24 Aug 2020 17:34:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:29:50', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4e21ae2c-628b-4813-aba6-d5092674fa55'	System	23 Aug 2020 01:29:58
User entered '1'	System	23 Aug 2020 01:29:58

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:14:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:29:50', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4e21ae2c-628b-4813-aba6-d5092674fa55'	System	23 Aug 2020 01:29:58
User entered '0'	System	23 Aug 2020 01:29:58

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:14:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:29:53', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4e21ae2c-628b-4813-aba6-d5092674fa55'	System	23 Aug 2020 01:29:58
User entered '22 Aug 2020 20:29'	System	23 Aug 2020 01:29:58

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 7'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:14:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:32:10', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '30ece766-4ab5-4752-aea0-f61addbc8466'	System	24 Aug 2020 00:32:23
User entered 'Yes (Y)'	System	24 Aug 2020 00:32:23

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:14:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:32:14', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '30ece766-4ab5-4752-aea0-f61adbbc8466'	System	24 Aug 2020 00:32:23
User entered '97.7'	System	24 Aug 2020 00:32:23

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:32:17', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '30ece766-4ab5-4752-aea0-f61addbc8466'	System	24 Aug 2020 00:32:23
User entered 'No (N)'	System	24 Aug 2020 00:32:23

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:14:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:32:19', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '30ece766-4ab5-4752-aea0-f61addbc8466'	System	24 Aug 2020 00:32:23
User entered '23 Aug 2020 19:32'	System	24 Aug 2020 00:32:23

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:47:25', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1a4573df-d338-416e-9de0-c5c9e9515329'	System	17 Aug 2020 17:48:24
User entered 'Does not interfere with activity (2)'	System	17 Aug 2020 17:48:24

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:47:44', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1a4573df-d338-416e-9de0-c5c9e9515329'	System	17 Aug 2020 17:48:24
User entered 'No (N)'	System	17 Aug 2020 17:48:24

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:48:12', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1a4573df-d338-416e-9de0-c5c9e9515329'	System	17 Aug 2020 17:48:24
User entered 'No (N)'	System	17 Aug 2020 17:48:24

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:48:18', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1a4573df-d338-416e-9de0-c5c9e9515329'	System	17 Aug 2020 17:48:24
User entered 'None (1)'	System	17 Aug 2020 17:48:24

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:48:22', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1a4573df-d338-416e-9de0-c5c9e9515329'	System	17 Aug 2020 17:48:24
User entered '17 Aug 2020 12:48'	System	17 Aug 2020 17:48:24

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '17 Aug 2020 12:26'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '17 Aug 2020 14:56'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4b3edb21-ff08-49a8-b9e9-7fe5adfc04ec'	System	18 Aug 2020 00:22:18
User entered 'None (1)'	System	18 Aug 2020 00:22:18

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:02', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4b3edb21-ff08-49a8-b9e9-7fe5adfc04ec'	System	18 Aug 2020 00:22:18
User entered 'No (N)'	System	18 Aug 2020 00:22:18

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:04', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4b3edb21-ff08-49a8-b9e9-7fe5adfc04ec'	System	18 Aug 2020 00:22:18
User entered 'No (N)'	System	18 Aug 2020 00:22:18

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:11', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4b3edb21-ff08-49a8-b9e9-7fe5adfc04ec'	System	18 Aug 2020 00:22:18
User entered 'None (1)'	System	18 Aug 2020 00:22:18

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:14', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4b3edb21-ff08-49a8-b9e9-7fe5adfc04ec'	System	18 Aug 2020 00:22:18
User entered '17 Aug 2020 19:22'	System	18 Aug 2020 00:22:18

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '17 Aug 2020 15:51'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 2'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:14:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:15:22', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '58416548-cdab-4ad5-ba54-3a02e7ff48b7'	System	19 Aug 2020 00:16:03
User entered 'None (1)'	System	19 Aug 2020 00:16:03

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:15:39', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '58416548-cdab-4ad5-ba54-3a02e7ff48b7'	System	19 Aug 2020 00:16:03
User entered 'No (N)'	System	19 Aug 2020 00:16:03

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:15:40', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '58416548-cdab-4ad5-ba54-3a02e7ff48b7'	System	19 Aug 2020 00:16:03
User entered 'No (N)'	System	19 Aug 2020 00:16:03

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:14:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:15:56', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '58416548-cdab-4ad5-ba54-3a02e7ff48b7'	System	19 Aug 2020 00:16:03
User entered 'None (1)'	System	19 Aug 2020 00:16:03

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:14:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:15:59', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '58416548-cdab-4ad5-ba54-3a02e7ff48b7'	System	19 Aug 2020 00:16:03
User entered '18 Aug 2020 19:15'	System	19 Aug 2020 00:16:03

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 3'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:14:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:09', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'dae1b8e9-28a6-4766-af41-de597c6189de'	System	20 Aug 2020 00:07:35
User entered 'None (1)'	System	20 Aug 2020 00:07:35

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:11', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'dae1b8e9-28a6-4766-af41-de597c6189de'	System	20 Aug 2020 00:07:35
User entered 'No (N)'	System	20 Aug 2020 00:07:35

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:15', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'dae1b8e9-28a6-4766-af41-de597c6189de'	System	20 Aug 2020 00:07:35
User entered 'No (N)'	System	20 Aug 2020 00:07:35

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:14:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:25', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'dae1b8e9-28a6-4766-af41-de597c6189de'	System	20 Aug 2020 00:07:35
User entered 'None (1)'	System	20 Aug 2020 00:07:35

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:14:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:30', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'dae1b8e9-28a6-4766-af41-de597c6189de'	System	20 Aug 2020 00:07:35
User entered '19 Aug 2020 19:07'	System	20 Aug 2020 00:07:35

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 4'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:14:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:26:21', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1fbf07e3-ec8c-451b-9322-0d6666796762'	System	21 Aug 2020 00:26:37
User entered 'None (1)'	System	21 Aug 2020 00:26:37

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:26:24', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1fbf07e3-ec8c-451b-9322-0d6666796762'	System	21 Aug 2020 00:26:37
User entered 'No (N)'	System	21 Aug 2020 00:26:37

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:26:26', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1fbf07e3-ec8c-451b-9322-0d6666796762'	System	21 Aug 2020 00:26:37
User entered 'No (N)'	System	21 Aug 2020 00:26:37

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:14:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:26:29', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1fbf07e3-ec8c-451b-9322-0d6666796762'	System	21 Aug 2020 00:26:37
User entered 'None (1)'	System	21 Aug 2020 00:26:37

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:14:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:26:31', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1fbf07e3-ec8c-451b-9322-0d6666796762'	System	21 Aug 2020 00:26:37
User entered '20 Aug 2020 19:26'	System	21 Aug 2020 00:26:37

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 5'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:14:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:06:27', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1e24dabc-be91-44fc-b39f-2b5591b0a0cb'	System	22 Aug 2020 01:06:44
User entered 'None (1)'	System	22 Aug 2020 01:06:44

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:06:30', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1e24dabc-be91-44fc-b39f-2b5591b0a0cb'	System	22 Aug 2020 01:06:44
User entered 'No (N)'	System	22 Aug 2020 01:06:44

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:06:36', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1e24dabc-be91-44fc-b39f-2b5591b0a0cb'	System	22 Aug 2020 01:06:44
User entered 'No (N)'	System	22 Aug 2020 01:06:44

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:14:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:06:39', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1e24dabc-be91-44fc-b39f-2b5591b0a0cb'	System	22 Aug 2020 01:06:44
User entered 'None (1)'	System	22 Aug 2020 01:06:44

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:14:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:06:41', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1e24dabc-be91-44fc-b39f-2b5591b0a0cb'	System	22 Aug 2020 01:06:44
User entered '21 Aug 2020 20:06'	System	22 Aug 2020 01:06:44

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 6'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:14:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:29:57', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '6bd9031b-6c3f-4eb2-ab19-383394f2ac5a'	System	23 Aug 2020 01:30:09
User entered 'None (1)'	System	23 Aug 2020 01:30:09

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:29:59', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '6bd9031b-6c3f-4eb2-ab19-383394f2ac5a'	System	23 Aug 2020 01:30:09
User entered 'No (N)'	System	23 Aug 2020 01:30:09

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:01', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '6bd9031b-6c3f-4eb2-ab19-383394f2ac5a'	System	23 Aug 2020 01:30:09
User entered 'No (N)'	System	23 Aug 2020 01:30:09

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:14:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:03', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '6bd9031b-6c3f-4eb2-ab19-383394f2ac5a'	System	23 Aug 2020 01:30:09
User entered 'None (1)'	System	23 Aug 2020 01:30:09

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:14:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:06', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '6bd9031b-6c3f-4eb2-ab19-383394f2ac5a'	System	23 Aug 2020 01:30:09
User entered '22 Aug 2020 20:30'	System	23 Aug 2020 01:30:09

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 7'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:14:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:32:30', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '9f1754ff-1b45-4a85-853c-7a5f5b494ead'	System	24 Aug 2020 00:33:01
User entered 'None (1)'	System	24 Aug 2020 00:33:01

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:32:33', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '9f1754ff-1b45-4a85-853c-7a5f5b494ead'	System	24 Aug 2020 00:33:01
User entered 'No (N)'	System	24 Aug 2020 00:33:01

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:32:36', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '9f1754ff-1b45-4a85-853c-7a5f5b494ead'	System	24 Aug 2020 00:33:01
User entered 'No (N)'	System	24 Aug 2020 00:33:01

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:14:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:32:56', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '9f1754ff-1b45-4a85-853c-7a5f5b494ead'	System	24 Aug 2020 00:33:01
User entered 'None (1)'	System	24 Aug 2020 00:33:01

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:14:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:32:58', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '9f1754ff-1b45-4a85-853c-7a5f5b494ead'	System	24 Aug 2020 00:33:01
User entered '23 Aug 2020 19:32'	System	24 Aug 2020 00:33:01

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:48:31', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'fb2308f7-3430-4500-b262-89741c502a5a'	System	17 Aug 2020 17:49:05
User entered 'No interference with activity (1)'	System	17 Aug 2020 17:49:05

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:48:38', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'fb2308f7-3430-4500-b262-89741c502a5a'	System	17 Aug 2020 17:49:05
User entered 'None (0)'	System	17 Aug 2020 17:49:05

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:48:42', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'fb2308f7-3430-4500-b262-89741c502a5a'	System	17 Aug 2020 17:49:05
User entered 'None (0)'	System	17 Aug 2020 17:49:05

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:48:46', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'fb2308f7-3430-4500-b262-89741c502a5a'	System	17 Aug 2020 17:49:05
User entered 'None (0)'	System	17 Aug 2020 17:49:05

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:48:49', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'fb2308f7-3430-4500-b262-89741c502a5a'	System	17 Aug 2020 17:49:05
User entered 'None (0)'	System	17 Aug 2020 17:49:05

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:48:53', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'fb2308f7-3430-4500-b262-89741c502a5a'	System	17 Aug 2020 17:49:05
User entered 'None (0)'	System	17 Aug 2020 17:49:05

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:48:59', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'fb2308f7-3430-4500-b262-89741c502a5a'	System	17 Aug 2020 17:49:05
User entered 'No (N)'	System	17 Aug 2020 17:49:05

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T12:49:02', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'fb2308f7-3430-4500-b262-89741c502a5a'	System	17 Aug 2020 17:49:05
User entered '17 Aug 2020 12:49'	System	17 Aug 2020 17:49:05

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '17 Aug 2020 12:26'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '17 Aug 2020 14:56'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:20', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b25cd7eb-2053-4508-9d34-4ea9202c5dae'	System	18 Aug 2020 00:22:45
User entered 'None (0)'	System	18 Aug 2020 00:22:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:23', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b25cd7eb-2053-4508-9d34-4ea9202c5dae'	System	18 Aug 2020 00:22:45
User entered 'None (0)'	System	18 Aug 2020 00:22:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:25', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b25cd7eb-2053-4508-9d34-4ea9202c5dae'	System	18 Aug 2020 00:22:45
User entered 'None (0)'	System	18 Aug 2020 00:22:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:26', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b25cd7eb-2053-4508-9d34-4ea9202c5dae'	System	18 Aug 2020 00:22:45
User entered 'None (0)'	System	18 Aug 2020 00:22:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:28', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b25cd7eb-2053-4508-9d34-4ea9202c5dae'	System	18 Aug 2020 00:22:45
User entered 'None (0)'	System	18 Aug 2020 00:22:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:30', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b25cd7eb-2053-4508-9d34-4ea9202c5dae'	System	18 Aug 2020 00:22:45
User entered 'None (0)'	System	18 Aug 2020 00:22:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:38', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b25cd7eb-2053-4508-9d34-4ea9202c5dae'	System	18 Aug 2020 00:22:45
User entered 'No (N)'	System	18 Aug 2020 00:22:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-17T19:22:43', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b25cd7eb-2053-4508-9d34-4ea9202c5dae'	System	18 Aug 2020 00:22:45
User entered '17 Aug 2020 19:22'	System	18 Aug 2020 00:22:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '17 Aug 2020 15:51'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 2'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:14:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:16:08', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b2eebed4-e76a-4d8f-8800-bd3482f754d3'	System	19 Aug 2020 00:16:26
User entered 'No interference with activity (1)'	System	19 Aug 2020 00:16:26

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:14:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:16:11', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b2eebed4-e76a-4d8f-8800-bd3482f754d3'	System	19 Aug 2020 00:16:26
User entered 'None (0)'	System	19 Aug 2020 00:16:26

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:14:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:16:13', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b2eebed4-e76a-4d8f-8800-bd3482f754d3'	System	19 Aug 2020 00:16:26
User entered 'None (0)'	System	19 Aug 2020 00:16:26

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:14:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:16:14', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b2eebed4-e76a-4d8f-8800-bd3482f754d3'	System	19 Aug 2020 00:16:26
User entered 'None (0)'	System	19 Aug 2020 00:16:26

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:14:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:16:16', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b2eebed4-e76a-4d8f-8800-bd3482f754d3'	System	19 Aug 2020 00:16:26
User entered 'None (0)'	System	19 Aug 2020 00:16:26

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:14:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:16:18', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b2eebed4-e76a-4d8f-8800-bd3482f754d3'	System	19 Aug 2020 00:16:26
User entered 'None (0)'	System	19 Aug 2020 00:16:26

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:16:21', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b2eebed4-e76a-4d8f-8800-bd3482f754d3'	System	19 Aug 2020 00:16:26
User entered 'No (N)'	System	19 Aug 2020 00:16:26

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:14:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-18T19:16:23', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b2eebed4-e76a-4d8f-8800-bd3482f754d3'	System	19 Aug 2020 00:16:26
User entered '18 Aug 2020 19:16'	System	19 Aug 2020 00:16:26

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 3'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:14:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:36', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '14de184c-d9cf-4abb-8f42-bdd722658c4c'	System	20 Aug 2020 00:08:01
User entered 'No interference with activity (1)'	System	20 Aug 2020 00:08:01

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:14:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:39', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '14de184c-d9cf-4abb-8f42-bdd722658c4c'	System	20 Aug 2020 00:08:01
User entered 'None (0)'	System	20 Aug 2020 00:08:01

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:14:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:45', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '14de184c-d9cf-4abb-8f42-bdd722658c4c'	System	20 Aug 2020 00:08:01
User entered 'None (0)'	System	20 Aug 2020 00:08:01

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:14:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:48', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '14de184c-d9cf-4abb-8f42-bdd722658c4c'	System	20 Aug 2020 00:08:01
User entered 'None (0)'	System	20 Aug 2020 00:08:01

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:14:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:50', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '14de184c-d9cf-4abb-8f42-bdd722658c4c'	System	20 Aug 2020 00:08:01
User entered 'None (0)'	System	20 Aug 2020 00:08:01

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:14:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:52', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '14de184c-d9cf-4abb-8f42-bdd722658c4c'	System	20 Aug 2020 00:08:01
User entered 'None (0)'	System	20 Aug 2020 00:08:01

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:55', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '14de184c-d9cf-4abb-8f42-bdd722658c4c'	System	20 Aug 2020 00:08:01
User entered 'No (N)'	System	20 Aug 2020 00:08:01

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:14:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-19T19:07:59', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '14de184c-d9cf-4abb-8f42-bdd722658c4c'	System	20 Aug 2020 00:08:01
User entered '19 Aug 2020 19:07'	System	20 Aug 2020 00:08:01

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 4'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:14:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:25:52', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b30f11bc-f30d-4893-b697-4d55517406bd'	System	21 Aug 2020 00:26:18
User entered 'No interference with activity (1)'	System	21 Aug 2020 00:26:18

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:14:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:25:59', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b30f11bc-f30d-4893-b697-4d55517406bd'	System	21 Aug 2020 00:26:18
User entered 'Some interference with activity (2)'	System	21 Aug 2020 00:26:18

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:14:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:26:04', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b30f11bc-f30d-4893-b697-4d55517406bd'	System	21 Aug 2020 00:26:18
User entered 'Some interference with activity (2)'	System	21 Aug 2020 00:26:18

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:14:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:26:07', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b30f11bc-f30d-4893-b697-4d55517406bd'	System	21 Aug 2020 00:26:18
User entered 'None (0)'	System	21 Aug 2020 00:26:18

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:14:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:26:09', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b30f11bc-f30d-4893-b697-4d55517406bd'	System	21 Aug 2020 00:26:18
User entered 'None (0)'	System	21 Aug 2020 00:26:18

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:14:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:26:10', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b30f11bc-f30d-4893-b697-4d55517406bd'	System	21 Aug 2020 00:26:18
User entered 'None (0)'	System	21 Aug 2020 00:26:18

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:26:14', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b30f11bc-f30d-4893-b697-4d55517406bd'	System	21 Aug 2020 00:26:18
User entered 'No (N)'	System	21 Aug 2020 00:26:18

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:14:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-20T19:26:16', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b30f11bc-f30d-4893-b697-4d55517406bd'	System	21 Aug 2020 00:26:18
User entered '20 Aug 2020 19:26'	System	21 Aug 2020 00:26:18

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 5'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:14:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:07:14', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '343a038f-fa7a-4b77-92f0-fca655d812a8'	System	22 Aug 2020 01:07:49
User entered 'No interference with activity (1)'	System	22 Aug 2020 01:07:49

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:14:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:07:20', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '343a038f-fa7a-4b77-92f0-fca655d812a8'	System	22 Aug 2020 01:07:49
User entered 'Some interference with activity (2)'	System	22 Aug 2020 01:07:49

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:14:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:07:25', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '343a038f-fa7a-4b77-92f0-fca655d812a8'	System	22 Aug 2020 01:07:49
User entered 'Some interference with activity (2)'	System	22 Aug 2020 01:07:49

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:14:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:07:31', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '343a038f-fa7a-4b77-92f0-fca655d812a8'	System	22 Aug 2020 01:07:49
User entered 'Some interference with activity (2)'	System	22 Aug 2020 01:07:49

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:14:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:07:40', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '343a038f-fa7a-4b77-92f0-fca655d812a8'	System	22 Aug 2020 01:07:49
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	22 Aug 2020 01:07:49

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:14:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:07:42', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '343a038f-fa7a-4b77-92f0-fca655d812a8'	System	22 Aug 2020 01:07:49
User entered 'None (0)'	System	22 Aug 2020 01:07:49

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:07:45', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '343a038f-fa7a-4b77-92f0-fca655d812a8'	System	22 Aug 2020 01:07:49
User entered 'No (N)'	System	22 Aug 2020 01:07:49

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:14:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-21T20:07:46', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '343a038f-fa7a-4b77-92f0-fca655d812a8'	System	22 Aug 2020 01:07:49
User entered '21 Aug 2020 20:07'	System	22 Aug 2020 01:07:49

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 6'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:14:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:14', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '17c4ff09-06c1-4d93-83b4-5f138e5656c4'	System	23 Aug 2020 01:30:54
User entered 'No interference with activity (1)'	System	23 Aug 2020 01:30:54

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:14:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:18', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '17c4ff09-06c1-4d93-83b4-5f138e5656c4'	System	23 Aug 2020 01:30:54
User entered 'No interference with activity (1)'	System	23 Aug 2020 01:30:54

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:14:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:21', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '17c4ff09-06c1-4d93-83b4-5f138e5656c4'	System	23 Aug 2020 01:30:54
User entered 'None (0)'	System	23 Aug 2020 01:30:54

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:14:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:26', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '17c4ff09-06c1-4d93-83b4-5f138e5656c4'	System	23 Aug 2020 01:30:54
User entered 'Some interference with activity (2)'	System	23 Aug 2020 01:30:54

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:14:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:37', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '17c4ff09-06c1-4d93-83b4-5f138e5656c4'	System	23 Aug 2020 01:30:54
User entered 'None (0)'	System	23 Aug 2020 01:30:54

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:14:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:38', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '17c4ff09-06c1-4d93-83b4-5f138e5656c4'	System	23 Aug 2020 01:30:54
User entered 'None (0)'	System	23 Aug 2020 01:30:54

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:49', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '17c4ff09-06c1-4d93-83b4-5f138e5656c4'	System	23 Aug 2020 01:30:54
User entered 'No (N)'	System	23 Aug 2020 01:30:54

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:14:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-22T20:30:51', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '17c4ff09-06c1-4d93-83b4-5f138e5656c4'	System	23 Aug 2020 01:30:54
User entered '22 Aug 2020 20:30'	System	23 Aug 2020 01:30:54

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 7'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:14:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:33:03', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1ef0f5ff-86c8-49e1-9849-9754576bb09b'	System	24 Aug 2020 00:33:24
User entered 'No interference with activity (1)'	System	24 Aug 2020 00:33:24

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:14:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:33:07', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1ef0f5ff-86c8-49e1-9849-9754576bb09b'	System	24 Aug 2020 00:33:24
User entered 'None (0)'	System	24 Aug 2020 00:33:24

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:14:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:33:10', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1ef0f5ff-86c8-49e1-9849-9754576bb09b'	System	24 Aug 2020 00:33:24
User entered 'None (0)'	System	24 Aug 2020 00:33:24

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:14:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:33:13', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1ef0f5ff-86c8-49e1-9849-9754576bb09b'	System	24 Aug 2020 00:33:24
User entered 'No interference with activity (1)'	System	24 Aug 2020 00:33:24

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:14:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:33:15', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1ef0f5ff-86c8-49e1-9849-9754576bb09b'	System	24 Aug 2020 00:33:24
User entered 'None (0)'	System	24 Aug 2020 00:33:24

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:14:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:33:17', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1ef0f5ff-86c8-49e1-9849-9754576bb09b'	System	24 Aug 2020 00:33:24
User entered 'None (0)'	System	24 Aug 2020 00:33:24

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:33:19', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1ef0f5ff-86c8-49e1-9849-9754576bb09b'	System	24 Aug 2020 00:33:24
User entered 'No (N)'	System	24 Aug 2020 00:33:24

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:14:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8a0987a97a70596a)', Time: '2020-08-23T19:33:21', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '1ef0f5ff-86c8-49e1-9849-9754576bb09b'	System	24 Aug 2020 00:33:24
User entered '23 Aug 2020 19:33'	System	24 Aug 2020 00:33:24

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	23 Aug 2020 01:30:54
User entered 'Day 8'	System	23 Aug 2020 01:30:54

US3322006

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27

US3322006

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:14:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27

US3322006

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 01:30:54

US3322006

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 01:30:54

US3322006

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	24 Aug 2020 00:33:24
User entered 'Day 9'	System	24 Aug 2020 00:33:24

US3322006

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27

US3322006

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:14:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27

US3322006

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 00:33:24

US3322006

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 00:33:24

US3322006

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	23 Aug 2020 01:30:54
User entered 'Day 8'	System	23 Aug 2020 01:30:54

US3322006

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27

US3322006

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:14:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27

US3322006

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 01:30:54

US3322006

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 01:30:54

US3322006

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	24 Aug 2020 00:33:24
User entered 'Day 9'	System	24 Aug 2020 00:33:24

US3322006

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27

US3322006

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:14:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27

US3322006

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 00:33:24

US3322006

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 00:33:24

US3322006

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	23 Aug 2020 01:29:58
User entered 'Day 8'	System	23 Aug 2020 01:29:58

US3322006

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27

US3322006

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:14:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27

US3322006

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '24 Aug 2020 12:00'	System	23 Aug 2020 01:29:58

US3322006

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '25 Aug 2020 11:59'	System	23 Aug 2020 01:29:58

US3322006

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
Data entry locked.	System	24 Aug 2020 00:33:24
User entered 'Day 9'	System	24 Aug 2020 00:33:24

US3322006

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27

US3322006

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:14:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27

US3322006

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:14:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 00:33:24

US3322006

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 11 Aug 2021 22:14:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 07:45:27
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 00:33:24

US3322006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	01 Sep 2020 13:16:30

US3322006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '24 Aug 2020'	Elisa Moralez (b) (4)	01 Sep 2020 13:16:30

US3322006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	01 Sep 2020 13:16:30

US3322006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	01 Sep 2020 13:16:30

US3322006

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	01 Sep 2020 13:16:34

US3322006

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered '1'	System	01 Sep 2020 13:16:34

US3322006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	01 Sep 2020 13:16:46

US3322006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '31 Aug 2020'	Elisa Moralez (b) (4)	01 Sep 2020 13:16:46

US3322006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	01 Sep 2020 13:16:46

US3322006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	01 Sep 2020 13:16:46

US3322006

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	01 Sep 2020 13:16:50

US3322006

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 06:31:58
User entered '1'	System	01 Sep 2020 13:16:50

US3322006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	14 Sep 2020 14:22:01

US3322006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 16:09:01
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'attempts made 9/10 and 9/11 unsuccessful ' (Site from System).	Elisa Moralez (b) (4) (b) (4)	14 Sep 2020 14:22:28
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Sep 2020 14:22:01
User entered '12 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	14 Sep 2020 14:22:01

US3322006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	14 Sep 2020 14:22:01

US3322006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	14 Sep 2020 14:22:01

US3322006

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	14 Sep 2020 14:22:33

US3322006

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered '1'	System	14 Sep 2020 14:22:33

US3322006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 16:41:28
User closed query 'Per progress note entered 18Sep20 during safety call on 12Sep20 subject was scheduled for illness visit. Please confirm with source and update accordingly.' (Site from CRA).		14 Feb 2021 22:40:59
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 19:40:26
Query 'Data is required. Please complete.' answered with 'monitor demanded it be removed' (Site from System).	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 19:40:08
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 19:40:00
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 19:40:00
Query 'Per progress note entered 18Sep20 during safety call on 12Sep20 subject was scheduled for illness visit. Please confirm with source and update accordingly.' answered with 'thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 15:28:20
User opened query 'Per progress note entered 18Sep20 during safety call on 12Sep20 subject was scheduled for illness visit. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 22:26:27
User closed query ' Please confirm visit as per protocol and source, subject was in convalescent period and should exit regular study schedule. ' (Site from CRA).		11 Feb 2021 22:26:27
Query ' Please confirm visit as per protocol and source, subject was in convalescent period and should exit regular study schedule. ' answered with 'visit was started, this is when patient confirmed reported symptoms, so available data was entered' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	10 Feb 2021 22:15:48
User opened query ' Please confirm visit as per protocol and source, subject was in convalescent period and should exit regular study schedule. ' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 18:22:41

US3322006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	07 Jan 2021 18:11:22

US3322006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty; reason for change Data Entry Error	(b) (4) Elisa Moralez (b) (4)	12 Feb 2021 19:40:00
User entered '12 Sep 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4)	12 Feb 2021 15:28:13
User entered '14 Sep 2020'	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:22

US3322006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty; reason for change Data Entry Error	(b) (4) Elisa Moralez (b) (4)	12 Feb 2021 19:40:00
User entered 'Clinic (Clinic)'	Frances Saubon (b) (4)	07 Jan 2021 18:11:22
	(b) (4)	

US3322006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered 'VISIT2'	System	12 Feb 2021 19:40:26
User entered empty.	System	12 Feb 2021 19:40:00
User entered 'VISIT2'	System	07 Jan 2021 18:11:22

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User accepted default value 'Pre-Dose (PREDOSE)'	Frances Saubon (b) (4) (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 16:41:37
Query 'Data is required. Please complete.' answered with 'monitor demanded all information be removed' (Site from System).	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 19:40:44
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 19:40:18
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 19:40:18
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered empty.	System	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered empty.	System	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered empty.	System	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered empty.	System	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered empty.	System	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User accepted default value 'Post-Dose (POSTDOSE)'	Frances Saubon (b) (4) (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 16:41:43
Query 'Data is required. Please complete.' answered with 'monitor demanded all information be removed' (Site from System).	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 19:40:47
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 19:40:18
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 19:40:18
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered empty.	System	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered empty.	System	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered empty.	System	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered empty.	System	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered empty.	System	07 Jan 2021 18:11:30

US3322006

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 16:41:46
Query 'Data is required. Please complete.' answered with 'monitor demanded all information be removed' (Site from System).	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 19:41:17
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 19:41:15
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 19:41:15
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	07 Jan 2021 18:11:35

US3322006

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	Frances Saubon (b) (4)	07 Jan 2021 18:11:35

US3322006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 16:41:49
Query 'Data is required. Please complete.' answered with 'monitor demanded all information be removed' (Site from System).	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 19:41:10
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 19:41:08
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 19:41:08
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	07 Jan 2021 18:11:53

US3322006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty; reason for change Data Entry Error	(b) (4) Elisa Moralez (b) (4)	12 Feb 2021 19:41:08
User entered 'Other (OTHER)'	Frances Saubon (b) (4)	07 Jan 2021 18:11:53
	(b) (4)	

US3322006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty; reason for change Data Entry Error	(b) (4) Elisa Moralez (b) (4)	12 Feb 2021 19:41:08
User entered 'Subject was moved to Illness Visit.'	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:11:53

US3322006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered empty.	System	07 Jan 2021 18:11:53

US3322006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	Frances Saubon (b) (4)	07 Jan 2021 18:11:53

US3322006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	Frances Saubon (b) (4)	07 Jan 2021 18:11:53

US3322006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered empty.	System	07 Jan 2021 18:11:53

US3322006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	Frances Saubon (b) (4)	07 Jan 2021 18:11:53

US3322006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered empty.	System	07 Jan 2021 18:11:53

US3322006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered empty.	System	07 Jan 2021 18:11:53

US3322006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 16:41:52
Query 'Data is required. Please complete.' answered with 'monitor demanded all information be removed' (Site from System).	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 19:41:25
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 19:41:23
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 19:41:23
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	07 Jan 2021 18:12:00

US3322006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	Frances Saubon (b) (4)	07 Jan 2021 18:12:00

US3322006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:12:00

US3322006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered empty.	System	07 Jan 2021 18:12:00

US3322006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:14:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:12:08

US3322006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:14:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Frances Saubon (b) (4) (b) (4)	07 Jan 2021 18:12:08

US3322006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:14:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 16:41:58
Query 'Data is required. Please complete.' answered with 'monitor demanded all information be removed' (Site from System).	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 19:41:36
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 19:41:32
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 19:41:32
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	07 Jan 2021 18:12:08

US3322006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:14:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:12:08

US3322006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:14:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered empty.	System	07 Jan 2021 18:12:08

US3322006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:14:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Frances Saubon (b) (4) (b) (4)	07 Jan 2021 18:12:08

US3322006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:14:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 16:42:01
Query 'Data is required. Please complete.' answered with 'monitor demanded all information be removed' (Site from System).	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 19:41:39
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 19:41:32
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 19:41:32
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	07 Jan 2021 18:12:08

US3322006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:14:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:12:08

US3322006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:14:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered empty.	System	07 Jan 2021 18:12:08

US3322006

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	07 Jan 2021 18:13:06

US3322006

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered '1'	System	07 Jan 2021 18:13:06

US3322006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	Elisa Moralez (b) (4)	25 Jan 2021 19:35:59

US3322006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	25 Jan 2021 19:35:59

US3322006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	25 Jan 2021 19:35:59

US3322006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Jan 2021 19:35:59

US3322006

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	13 Jan 2021 19:08:23

US3322006

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered '1'	System	13 Jan 2021 19:08:23

US3322006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Jan 2021 19:39:02

US3322006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	25 Jan 2021 19:39:02

US3322006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	25 Jan 2021 19:39:02

US3322006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Jan 2021 19:39:02

US3322006

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	13 Jan 2021 19:08:33

US3322006

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered '1'	System	13 Jan 2021 19:08:33

US3322006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	Elisa Moralez (b) (4)	25 Jan 2021 19:40:11

US3322006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	25 Jan 2021 19:40:11

US3322006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	25 Jan 2021 19:40:11

US3322006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Jan 2021 19:40:11

US3322006

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	13 Jan 2021 19:08:40

US3322006

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered '1'	System	13 Jan 2021 19:08:40

US3322006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered 'No (N)'	Elisa Moralez (b) (4)	25 Jan 2021 19:54:46

US3322006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	Elisa Moralez (b) (4)	25 Jan 2021 19:54:46

US3322006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered empty.	Elisa Moralez (b) (4)	25 Jan 2021 19:54:46

US3322006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered 'VISIT3'	System	25 Jan 2021 19:54:46

US3322006

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:55:08
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	13 Jan 2021 19:08:49

US3322006

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered '1'	System	13 Jan 2021 19:08:49

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 64'	System	17 Aug 2020 17:08:45

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Please 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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Please 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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Please 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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57
Data entry locked.	System	17 Aug 2020 17:08:45
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 17:08:45

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57
Data entry locked.	System	17 Aug 2020 17:08:45
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 71'	System	17 Aug 2020 17:08:45

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Please 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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
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US3322006

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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)	24 Apr 2021 06:08:00
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US3322006

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

Audit	User	Time (GMT)
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US3322006

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[Date and time of submission](#)

Audit	User	Time (GMT)
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57
Data entry locked.	System	17 Aug 2020 17:08:45
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 17:08:45

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57
Data entry locked.	System	17 Aug 2020 17:08:45
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 78'	System	17 Aug 2020 17:08:45

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Please 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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Please 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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57
Data entry locked.	System	17 Aug 2020 17:08:45
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 17:08:45

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57
Data entry locked.	System	17 Aug 2020 17:08:45
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57
Data entry locked.	System	17 Aug 2020 17:08:45
User entered 'Day 92'	System	17 Aug 2020 17:08:45

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Please 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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Please 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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Please 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)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57
Data entry locked.	System	17 Aug 2020 17:08:45
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 17:08:45

US3322006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:10:57
Data entry locked.	System	17 Aug 2020 17:08:45
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 17:08:45

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (6599ed0d921f632a)', Time: '2020-12-02T13:59:14', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '5cadf836-413a-4f35-b9fd-5ec537b9fe9f'	System	02 Dec 2020 19:59:59
User entered 'Yes (Y)'	System	02 Dec 2020 19:59:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (6599ed0d921f632a)', Time: '2020-12-02T13:59:21', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '5cadf836-413a-4f35-b9fd-5ec537b9fe9f'	System	02 Dec 2020 19:59:59
User entered 'No (N)'	System	02 Dec 2020 19:59:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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 (6599ed0d921f632a)', Time: '2020-12-02T13:59:44', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '5cadf836-413a-4f35-b9fd-5ec537b9fe9f'	System	02 Dec 2020 19:59:59
User entered 'No (N)'	System	02 Dec 2020 19:59:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

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 (6599ed0d921f632a)', Time: '2020-12-02T13:59:47', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '5cadf836-413a-4f35-b9fd-5ec537b9fe9f'	System	02 Dec 2020 19:59:59
User entered 'No (N)'	System	02 Dec 2020 19:59:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2020-12-02T13:59:52', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '5cadf836-413a-4f35-b9fd-5ec537b9fe9f' User entered '02 Dec 2020 13:59:52'	System	02 Dec 2020 19:59:59
	System	02 Dec 2020 19:59:59

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (6599ed0d921f632a)', Time: '2020-12-10T09:09:33', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '517f93df-3d2f-4389-b524-9b29cc027693'	System	10 Dec 2020 15:09:54
User entered 'No (N)'	System	10 Dec 2020 15:09:54

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (6599ed0d921f632a)', Time: '2020-12-10T09:09:41', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '517f93df-3d2f-4389-b524-9b29cc027693'	System	10 Dec 2020 15:09:54
User entered 'No (N)'	System	10 Dec 2020 15:09:54

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2020-12-10T09:09:50', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '517f93df-3d2f-4389-b524-9b29cc027693'	System	10 Dec 2020 15:09:54
User entered '10 Dec 2020 09:09:50'	System	10 Dec 2020 15:09:54

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (6599ed0d921f632a)', Time: '2020-12-17T12:30:40', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '007cc09a-f98c-40a8-91bd-6c554a3a4c46'	System	17 Dec 2020 18:30:55
User entered 'No (N)'	System	17 Dec 2020 18:30:55

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (6599ed0d921f632a)', Time: '2020-12-17T12:30:43', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '007cc09a-f98c-40a8-91bd-6c554a3a4c46'	System	17 Dec 2020 18:30:55
User entered 'No (N)'	System	17 Dec 2020 18:30:55

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2020-12-17T12:30:49', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '007cc09a-f98c-40a8-91bd-6c554a3a4c46'	System	17 Dec 2020 18:30:55
User entered '17 Dec 2020 12:30:49'	System	17 Dec 2020 18:30:55

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (6599ed0d921f632a)', Time: '2020-12-24T07:59:29', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '8e8d9514-0d1f-4d44-8b91-e7a66327e5f5'	System	24 Dec 2020 13:59:40
User entered 'No (N)'	System	24 Dec 2020 13:59:40

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (6599ed0d921f632a)', Time: '2020-12-24T07:59:32', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '8e8d9514-0d1f-4d44-8b91-e7a66327e5f5'	System	24 Dec 2020 13:59:40
User entered 'No (N)'	System	24 Dec 2020 13:59:40

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2020-12-24T07:59:36', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '8e8d9514-0d1f-4d44-8b91-e7a66327e5f5'	System	24 Dec 2020 13:59:40
User entered '24 Dec 2020 07:59:36'	System	24 Dec 2020 13:59:40

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (6599ed0d921f632a)', Time: '2020-12-30T05:00:32', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'e24f87be-52e5-443a-954e-70a102e39bb6'	System	30 Dec 2020 11:00:45
User entered 'No (N)'	System	30 Dec 2020 11:00:45

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (6599ed0d921f632a)', Time: '2020-12-30T05:00:38', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'e24f87be-52e5-443a-954e-70a102e39bb6'	System	30 Dec 2020 11:00:45
User entered 'No (N)'	System	30 Dec 2020 11:00:45

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2020-12-30T05:00:43', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'e24f87be-52e5-443a-954e-70a102e39bb6'	System	30 Dec 2020 11:00:45
User entered '30 Dec 2020 05:00:43'	System	30 Dec 2020 11:00:45

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (6599ed0d921f632a)', Time: '2021-01-06T07:52:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '700c3b40-0b0e-4dd3-a284-0a8a8cd8d9c9'	System	06 Jan 2021 14:00:48
User entered 'No (N)'	System	06 Jan 2021 14:00:48

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (6599ed0d921f632a)', Time: '2021-01-06T07:52:03', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '700c3b40-0b0e-4dd3-a284-0a8a8cd8d9c9'	System	06 Jan 2021 14:00:48
User entered 'No (N)'	System	06 Jan 2021 14:00:48

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2021-01-06T07:52:07', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '700c3b40-0b0e-4dd3-a284-0a8a8cd8d9c9' User entered '06 Jan 2021 07:52:07'	System	06 Jan 2021 14:00:48
	System	06 Jan 2021 14:00:48

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (6599ed0d921f632a)', Time: '2021-01-13T08:37:11', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '171e4e23-8984-4a57-8b55-4b593565aaec'	System	13 Jan 2021 14:37:22
User entered 'No (N)'	System	13 Jan 2021 14:37:22

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (6599ed0d921f632a)', Time: '2021-01-13T08:37:14', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '171e4e23-8984-4a57-8b55-4b593565aaec'	System	13 Jan 2021 14:37:22
User entered 'No (N)'	System	13 Jan 2021 14:37:22

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2021-01-13T08:37:17', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '171e4e23-8984-4a57-8b55-4b593565aaec' User entered '13 Jan 2021 08:37:17'	System	13 Jan 2021 14:37:22

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (6599ed0d921f632a)', Time: '2021-01-20T03:48:12', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '49f822b3-9574-4364-8396-65fc88e50ab2'	System	20 Jan 2021 09:48:25
User entered 'No (N)'	System	20 Jan 2021 09:48:25

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (6599ed0d921f632a)', Time: '2021-01-20T03:48:18', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '49f822b3-9574-4364-8396-65fc88e50ab2'	System	20 Jan 2021 09:48:25
User entered 'No (N)'	System	20 Jan 2021 09:48:25

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2021-01-20T03:48:21', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '49f822b3-9574-4364-8396-65fc88e50ab2'	System	20 Jan 2021 09:48:25
User entered '20 Jan 2021 03:48:21'	System	20 Jan 2021 09:48:25

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (6599ed0d921f632a)', Time: '2021-01-27T09:27:53', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4f00f1ba-dee2-4eac-b24a-bbc310e75c95'	System	27 Jan 2021 15:28:04
User entered 'No (N)'	System	27 Jan 2021 15:28:04

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (6599ed0d921f632a)', Time: '2021-01-27T09:27:58', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4f00f1ba-dee2-4eac-b24a-bbc310e75c95'	System	27 Jan 2021 15:28:04
User entered 'No (N)'	System	27 Jan 2021 15:28:04

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2021-01-27T09:28:02', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '4f00f1ba-dee2-4eac-b24a-bbc310e75c95'	System	27 Jan 2021 15:28:04
User entered '27 Jan 2021 09:28:02'	System	27 Jan 2021 15:28:04

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (6599ed0d921f632a)', Time: '2021-02-03T01:41:28', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b69fb570-3ee6-495f-ae76-dc278c06c0b1'	System	03 Feb 2021 07:41:37
User entered 'No (N)'	System	03 Feb 2021 07:41:37

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (6599ed0d921f632a)', Time: '2021-02-03T01:41:32', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b69fb570-3ee6-495f-ae76-dc278c06c0b1'	System	03 Feb 2021 07:41:37
User entered 'No (N)'	System	03 Feb 2021 07:41:37

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2021-02-03T01:41:35', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b69fb570-3ee6-495f-ae76-dc278c06c0b1'	System	03 Feb 2021 07:41:37
User entered '03 Feb 2021 01:41:35'	System	03 Feb 2021 07:41:37

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (6599ed0d921f632a)', Time: '2021-02-10T03:24:11', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '9b1fe07e-d4d8-40ab-8753-5d27e7eaf8ab'	System	10 Feb 2021 09:24:29
User entered 'No (N)'	System	10 Feb 2021 09:24:29

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (6599ed0d921f632a)', Time: '2021-02-10T03:24:16', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '9b1fe07e-d4d8-40ab-8753-5d27e7eaf8ab'	System	10 Feb 2021 09:24:29
User entered 'No (N)'	System	10 Feb 2021 09:24:29

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2021-02-10T03:24:23', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '9b1fe07e-d4d8-40ab-8753-5d27e7eaf8ab' User entered '10 Feb 2021 03:24:23'	System	10 Feb 2021 09:24:29
	System	10 Feb 2021 09:24:29

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (6599ed0d921f632a)', Time: '2021-02-18T02:27:35', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'e4e83389-294f-49a7-bcba-8f1b945bc95a'	System	18 Feb 2021 08:27:49
User entered 'No (N)'	System	18 Feb 2021 08:27:49

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (6599ed0d921f632a)', Time: '2021-02-18T02:27:38', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'e4e83389-294f-49a7-bcba-8f1b945bc95a'	System	18 Feb 2021 08:27:49
User entered 'No (N)'	System	18 Feb 2021 08:27:49

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2021-02-18T02:27:46', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'e4e83389-294f-49a7-bcba-8f1b945bc95a'	System	18 Feb 2021 08:27:49
User entered '18 Feb 2021 02:27:46'	System	18 Feb 2021 08:27:49

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (6599ed0d921f632a)', Time: '2021-02-24T03:45:10-06:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'ff06fce3-c82e-4160-a356-c1bbc761fb8c'	System	24 Feb 2021 09:45:24
User entered 'No (N)'	System	24 Feb 2021 09:45:24

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (6599ed0d921f632a)', Time: '2021-02-24T03:45:14-06:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'ff06fce3-c82e-4160-a356-c1bbc761fb8c'	System	24 Feb 2021 09:45:24
User entered 'No (N)'	System	24 Feb 2021 09:45:24

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2021-02-24T03:45:22-06:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'ff06fce3-c82e-4160-a356-c1bbc761fb8c' User entered '24 Feb 2021 03:45:22'	System	24 Feb 2021 09:45:24
	System	24 Feb 2021 09:45:24

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (6599ed0d921f632a)', Time: '2021-03-03T03:25:00-06:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '22265f19-b39b-4c9f-81ae-178f3dd135ce'	System	03 Mar 2021 09:25:10
User entered 'No (N)'	System	03 Mar 2021 09:25:10

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (6599ed0d921f632a)', Time: '2021-03-03T03:25:02-06:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '22265f19-b39b-4c9f-81ae-178f3dd135ce'	System	03 Mar 2021 09:25:10
User entered 'No (N)'	System	03 Mar 2021 09:25:10

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2021-03-03T03:25:04-06:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '22265f19-b39b-4c9f-81ae-178f3dd135ce' User entered '03 Mar 2021 03:25:04'	System	03 Mar 2021 09:25:10
	System	03 Mar 2021 09:25:10

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (6599ed0d921f632a)', Time: '2021-03-11T02:17:21-06:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '35ed3afe-0d05-49f5-ad8c-1c01fc1bbd0c'	System	11 Mar 2021 08:17:28
User entered 'No (N)'	System	11 Mar 2021 08:17:28

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (6599ed0d921f632a)', Time: '2021-03-11T02:17:24-06:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '35ed3afe-0d05-49f5-ad8c-1c01fc1bbd0c'	System	11 Mar 2021 08:17:28
User entered 'No (N)'	System	11 Mar 2021 08:17:28

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2021-03-11T02:17:27-06:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '35ed3afe-0d05-49f5-ad8c-1c01fc1bbd0c' User entered '11 Mar 2021 02:17:27'	System	11 Mar 2021 08:17:28
	System	11 Mar 2021 08:17:28

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (6599ed0d921f632a)', Time: '2021-03-17T10:11:19-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'ade9d38b-6aef-44a0-b6d3-1623c158b917'	System	17 Mar 2021 15:11:29
User entered 'No (N)'	System	17 Mar 2021 15:11:29

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (6599ed0d921f632a)', Time: '2021-03-17T10:11:21-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'ade9d38b-6aef-44a0-b6d3-1623c158b917'	System	17 Mar 2021 15:11:29
User entered 'No (N)'	System	17 Mar 2021 15:11:29

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2021-03-17T10:11:23-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'ade9d38b-6aef-44a0-b6d3-1623c158b917' User entered '17 Mar 2021 10:11:23'	System	17 Mar 2021 15:11:29
	System	17 Mar 2021 15:11:29

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (6599ed0d921f632a)', Time: '2021-03-24T22:38:20-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '9edd0fc0-e8de-4a09-ba8b-d00bdb822d3c'	System	25 Mar 2021 03:38:23
User entered 'No (N)'	System	25 Mar 2021 03:38:23

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (6599ed0d921f632a)', Time: '2021-03-24T22:38:22-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '9edd0fc0-e8de-4a09-ba8b-d00bdb822d3c'	System	25 Mar 2021 03:38:23
User entered 'No (N)'	System	25 Mar 2021 03:38:23

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2021-03-24T22:38:24-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '9edd0fc0-e8de-4a09-ba8b-d00bdb822d3c' User entered '24 Mar 2021 22:38:24'	System	25 Mar 2021 03:38:23

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (6599ed0d921f632a)', Time: '2021-03-31T17:56:24-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '94faef36-745b-48e5-9103-830e6368c07d'	System	31 Mar 2021 22:56:27
User entered 'No (N)'	System	31 Mar 2021 22:56:27

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (6599ed0d921f632a)', Time: '2021-03-31T17:56:26-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '94faef36-745b-48e5-9103-830e6368c07d'	System	31 Mar 2021 22:56:27
User entered 'No (N)'	System	31 Mar 2021 22:56:27

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2021-03-31T17:56:28-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '94faef36-745b-48e5-9103-830e6368c07d' User entered '31 Mar 2021 17:56:28'	System	31 Mar 2021 22:56:27
	System	31 Mar 2021 22:56:27

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (6599ed0d921f632a)', Time: '2021-04-09T03:02:56-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '10b0fd50-3402-4bf3-8120-09bd547c8bc0'	System	09 Apr 2021 08:03:01
User entered 'No (N)'	System	09 Apr 2021 08:03:01

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (6599ed0d921f632a)', Time: '2021-04-09T03:02:59-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '10b0fd50-3402-4bf3-8120-09bd547c8bc0'	System	09 Apr 2021 08:03:01
User entered 'No (N)'	System	09 Apr 2021 08:03:01

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2021-04-09T03:03:01-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '10b0fd50-3402-4bf3-8120-09bd547c8bc0' User entered '09 Apr 2021 03:03:01'	System	09 Apr 2021 08:03:01
	System	09 Apr 2021 08:03:01

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (BE86A6FC-1330-4258-B066-B885B73BC35F)', Time: '2021-04-15T15:46:41-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '857da42f-629a-46c2-9372-375ab89189c9'	System	15 Apr 2021 20:46:52
User entered 'No (N)'	System	15 Apr 2021 20:46:52

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (BE86A6FC-1330-4258-B066-B885B73BC35F)', Time: '2021-04-15T15:46:44-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '857da42f-629a-46c2-9372-375ab89189c9'	System	15 Apr 2021 20:46:52
User entered 'No (N)'	System	15 Apr 2021 20:46:52

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE86A6FC-1330-4258-B066-B885B73BC35F)', Time: '2021-04-15T15:46:48-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '857da42f-629a-46c2-9372-375ab89189c9'	System	15 Apr 2021 20:46:52
User entered '15 Apr 2021 15:46:48'	System	15 Apr 2021 20:46:52

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (BE86A6FC-1330-4258-B066-B885B73BC35F)', Time: '2021-04-21T15:57:54-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '014b7a1b-ef6f-43f9-8ce6-6f9c6e20f6e5'	System	21 Apr 2021 20:58:14
User entered 'No (N)'	System	21 Apr 2021 20:58:14

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (BE86A6FC-1330-4258-B066-B885B73BC35F)', Time: '2021-04-21T15:57:37-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '014b7a1b-ef6f-43f9-8ce6-6f9c6e20f6e5'	System	21 Apr 2021 20:58:14
User entered 'No (N)'	System	21 Apr 2021 20:58:14

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE86A6FC-1330-4258-B066-B885B73BC35F)', Time: '2021-04-21T15:58:03-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: '014b7a1b-ef6f-43f9-8ce6-6f9c6e20f6e5'	System	21 Apr 2021 20:58:14
User entered '21 Apr 2021 15:58:03'	System	21 Apr 2021 20:58:14

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[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 (BE86A6FC-1330-4258-B066-B885B73BC35F)', Time: '2021-04-28T04:34:28-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'bb3c71f4-91ca-4b10-920d-fa6915d27b61'	System	28 Apr 2021 20:45:09
User entered 'No (N)'	System	28 Apr 2021 20:45:09

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

Have you been exposed to someone with 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 (BE86A6FC-1330-4258-B066-B885B73BC35F)', Time: '2021-04-28T04:34:30-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'bb3c71f4-91ca-4b10-920d-fa6915d27b61'	System	28 Apr 2021 20:45:09
User entered 'No (N)'	System	28 Apr 2021 20:45:09

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (BE86A6FC-1330-4258-B066-B885B73BC35F)', Time: '2021-04-28T04:34:35-05:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'bb3c71f4-91ca-4b10-920d-fa6915d27b61'	System	28 Apr 2021 20:45:09
User entered '28 Apr 2021 04:34:35'	System	28 Apr 2021 20:45:09

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 08:10:57

US3322006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:14:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:10:57
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 08:10:57

US3322006

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:14:11

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 06:08:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2021-03-02T20:12:19-06:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b1189a2f-46b4-4cb8-9136-b02fa46a7f22'	System	03 Mar 2021 02:19:49
User entered 'No (N)'	System	03 Mar 2021 02:19:49

US3322006

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:14:11

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:08:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6599ed0d921f632a)', Time: '2021-03-02T20:12:23-06:00', User OID: 'PatientReportedOutcome (US3322006)', ODM File OID: 'b1189a2f-46b4-4cb8-9136-b02fa46a7f22'	System	03 Mar 2021 02:19:49
User entered '02 Mar 2021 20:12:23'	System	03 Mar 2021 02:19:49

US3322006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	Elisa Moralez (b) (4)	25 Jan 2021 19:43:25

US3322006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	25 Jan 2021 19:43:25

US3322006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	25 Jan 2021 19:43:25

US3322006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Elisa Moralez (b) (4)	25 Jan 2021 19:43:25
	(b) (4)	

US3322006

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	13 Jan 2021 19:09:01

US3322006

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	09 Apr 2021 20:21:28
User entered '1'	System	13 Jan 2021 19:09:01

US3322006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:39:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	13 Jan 2021 19:09:23

US3322006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:39:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '10 Dec 2020'	Elisa Moralez (b) (4)	13 Jan 2021 19:09:23

US3322006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:39:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	13 Jan 2021 19:09:23

US3322006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:39:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Elisa Moralez (b) (4)	13 Jan 2021 19:09:23
	(b) (4)	

US3322006

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:39:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	13 Jan 2021 19:09:12

US3322006

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:39:20
User entered '1'	System	13 Jan 2021 19:09:12

US3322006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:39:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	13 Jan 2021 19:09:32

US3322006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:39:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '12 Jan 2021'	Elisa Moralez (b) (4)	13 Jan 2021 19:09:32

US3322006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:39:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	13 Jan 2021 19:09:32

US3322006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:39:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Elisa Moralez (b) (4)	13 Jan 2021 19:09:32
	(b) (4)	

US3322006

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:39:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	13 Jan 2021 19:09:37

US3322006

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:39:20
User entered '1'	System	13 Jan 2021 19:09:37

US3322006

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:39:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	20 Feb 2021 22:27:09

US3322006

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:39:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '09 Feb 2021'	Elisa Moralez (b) (4)	20 Feb 2021 22:27:09

US3322006

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:39:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	20 Feb 2021 22:27:09

US3322006

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:39:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Elisa Moralez (b) (4)	20 Feb 2021 22:27:09
	(b) (4)	

US3322006

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:39:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	20 Feb 2021 22:27:13

US3322006

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:39:20
User entered '1'	System	20 Feb 2021 22:27:13

US3322006

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4)	24 Mar 2021 19:46:36

US3322006

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered '24 Mar 2021'	Elisa Moralez (b) (4)	24 Mar 2021 19:46:36

US3322006

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[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 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4)	24 Mar 2021 19:46:36

US3322006

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered 'VISIT4'	System	24 Mar 2021 19:46:36

US3322006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
User entered 'No (N)'	Elisa Moralez (b) (4)	31 Mar 2021 14:55:56

US3322006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
User entered empty.	Elisa Moralez (b) (4)	31 Mar 2021 14:55:56

US3322006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
User entered empty.	Elisa Moralez (b) (4)	31 Mar 2021 14:55:56

US3322006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	31 Mar 2021 14:55:56

US3322006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
User entered empty.	Elisa Moralez (b) (4)	31 Mar 2021 14:55:56

US3322006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
User entered empty.	Elisa Moralez (b) (4)	31 Mar 2021 14:55:56

US3322006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	31 Mar 2021 14:55:56

US3322006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
User entered empty.	(b) (4) Elisa Moralez (b) (4)	31 Mar 2021 14:55:56

US3322006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	31 Mar 2021 14:55:56

US3322006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
User entered empty.	Elisa Moralez (b) (4)	31 Mar 2021 14:55:56

US3322006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	31 Mar 2021 14:55:56

US3322006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
User entered empty.	Elisa Moralez (b) (4)	31 Mar 2021 14:55:56

US3322006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	31 Mar 2021 14:55:56

US3322006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	31 Mar 2021 14:55:56

US3322006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered empty.	System	31 Mar 2021 14:55:56

US3322006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11

US3322006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11

US3322006

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered 'No (N)'	Elisa Moralez (b) (4)	24 Mar 2021 19:46:38

US3322006

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered empty.	(b) (4) Elisa Moralez (b) (4)	24 Mar 2021 19:46:38

US3322006

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:17:57
User closed query 'Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Immunogenicity Assessment" is recorded here as NO but in OL-D57 it is captured. Please clarify why there is a difference or update the field. Thank you! ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Apr 2021 17:19:39
Query 'Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Immunogenicity Assessment" is recorded here as NO but in OL-D57 it is captured. Please clarify why there is a difference or update the field. Thank you! ' answered with 'done' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	05 Apr 2021 20:16:40
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	05 Apr 2021 20:16:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	05 Apr 2021 20:16:34
User opened query 'Per CDM: Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Immunogenicity Assessment" is recorded here as NO but in OL-D57 it is captured. Please clarify why there is a difference or update the field. Thank you! ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 18:25:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 21:49:41
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	24 Mar 2021 19:46:42

US3322006

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:17:57
Signature has been broken.	(b) (4) Elisa Moralez (b) (4)	05 Apr 2021 20:16:34
User entered '24 Mar 2021' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	05 Apr 2021 20:16:34
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered empty.	(b) (4) Elisa Moralez (b) (4)	24 Mar 2021 19:46:42

US3322006

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:17:57
Signature has been broken.	Elisa Moralez (b) (4)	05 Apr 2021 20:16:34
User entered '11:52' reason for change: Data Entry Error	Elisa Moralez (b) (4)	05 Apr 2021 20:16:34
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered empty.	Elisa Moralez (b) (4)	24 Mar 2021 19:46:42

US3322006

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered '24 Mar 2021 11:52'	System	05 Apr 2021 20:16:34
User entered empty.	System	24 Mar 2021 19:46:42

US3322006

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	24 Mar 2021 19:46:44

US3322006

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:58:11
User entered '1'	System	24 Mar 2021 19:46:44

US3322006

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:17:57
User entered 'Yes (Y)'	(b) (4) Elisa Morales (b) (4)	19 Apr 2021 15:04:07
	(b) (4)	

US3322006

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:17:57
User entered '09 Apr 2021'	(b) (4) Elisa Morales (b) (4)	19 Apr 2021 15:04:07
	(b) (4)	

US3322006

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:17:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Morales (b) (4) (b) (4)	19 Apr 2021 15:04:07

US3322006

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:17:57
User entered empty.	(b) (4) Elisa Moralez (b) (4)	19 Apr 2021 15:04:07
	(b) (4)	

US3322006

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:17:57
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4)	19 Apr 2021 15:04:10
	(b) (4)	

US3322006

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 15:04:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:14:11

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:16
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Per response, since an additional swab was collected and in EDC, additional swab can be recorded only under COVID-19 Assessment visit-COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form. Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 08:17:55
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Per response, since an additional swab was collected and in EDC, additional swab can be recorded only under COVID-19 Assessment visit-COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form. Thank you.' answered with 'Thank you for the clarification, a separate COVID visit has been added with visit date 08OCT2020, please inactivate the symptom log page to confirm correct entry as there are no symptoms that are not already recorded in the 14SEP2020 illness visit. Thank you!' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 13:30:51
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Per response, since an additional swab was collected and in EDC, additional swab can be recorded only under COVID-19 Assessment visit-COVID diagnostic form. Please review and initiate a COVID-19 Assessment visit and record the swab under COVID Diagnostic form. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 06:47:28
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 08-OCT-2020 is recorded under Illness Visit Day 28 in PPD portal; however, swab sample for 08-OCT-2020 is missing in EDC. Kindly consider initiating separate Covid-19 Assessment eCRF for 08-OCT-2020 and update swab data in COVID Diagnostic Test eCRF. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 06:47:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:14:11

[Date of Contact](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 08-OCT-2020 is recorded under Illness Visit Day 28 in PPD portal; however, swab sample for 08-OCT-2020 is missing in EDC. Kindly consider initiating separate Covid-19 Assessment eCRF for 08-OCT-2020 and update swab data in COVID Diagnostic Test eCRF. Else clarify, thank you.' answered with 'Please clarify which swab sample is missing in EDC, as in the illness visit, there is not a page for Nasal Swab. However, blood sample is entered with the correct date, as is the saliva collection sample in the saliva collection page.' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	31 Mar 2021 13:19:12
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 08-OCT-2020 is recorded under Illness Visit Day 28 in PPD portal; however, swab sample for 08-OCT-2020 is missing in EDC. Kindly consider initiating separate Covid-19 Assessment eCRF for 08-OCT-2020 and update swab data in COVID Diagnostic Test eCRF. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 12:48:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 19:47:14
User entered '14 Sep 2020' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:01:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 07:16:30
Query 'Data is required. Please complete.' answered with 'form filled out in error' (Site from System).	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:03:14
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 19:02:56
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:56
User entered '9 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 19:57:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:14:11

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 19:47:14
User entered '00:00' reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:01:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 07:22:42
Query 'Data is required. Please complete.' answered with 'form filled out in error' (Site from System).	Elisa Moralez (b) (4)	16 Sep 2020 19:03:16
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	16 Sep 2020 19:02:56
User entered '00:00'	Elisa Moralez (b) (4)	16 Sep 2020 19:02:56
	(b) (4)	
	Elisa Moralez (b) (4)	15 Sep 2020 19:57:29
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:14:11

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:16
User entered '14 Sep 2020 00:00'	System	21 Sep 2020 20:01:35
User entered empty.	System	16 Sep 2020 19:02:56
User entered '9 Sep 2020 00:00'	System	15 Sep 2020 19:57:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:14:11

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 19:47:14
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:01:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 07:22:44
Query 'Data is required. Please complete.' answered with 'form filled out in error' (Site from System).	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:03:24
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 19:02:56
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:56
User entered 'Safety Call (Safety Call)'	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 19:57:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:14:11

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 19:47:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Frances Saubon (b) (4)	21 Sep 2020 20:01:35
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 07:22:46
Query 'Data is required. Please complete.' answered with 'form filled out in error' (Site from System).	Elisa Moralez (b) (4)	16 Sep 2020 19:03:21
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	16 Sep 2020 19:02:56
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	16 Sep 2020 19:02:56
	(b) (4)	
	Elisa Moralez (b) (4)	15 Sep 2020 19:57:29
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint activated with code reason code Data required.	(b) (4) Elisa Moralez (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	(b) (4) Elisa Moralez (b) (4)	16 Sep 2020 19:02:27
User entered 'Day 1 (Day 1)'	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered '9 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered '1'	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	System	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:09:07
DataPoint inactivated with code reason code Data not required.	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:02:27
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:04:04

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	28 Sep 2020 21:56:48
User entered 'Day 2 (Day 2)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '15 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User closed query 'Per multiple query responses on this page site was unable to reach subject and didn't speak to them on 15Spe2020. Please consider removing all fields noted as NONE and instead click assessment not done box.' (Site from CRA).		12 Nov 2020 01:04:24
Query 'Per multiple query responses on this page site was unable to reach subject and didn't speak to them on 15Spe2020. Please consider removing all fields noted as NONE and instead click assessment not done box.' answered with 'Per source, contact was made on 15-Sep-2020 but it was documented on the 16-Sep-2020 since the Symptom, Temperature, and Oxygen were not reported until late evening(patient did not have access to her thermometer and O2 machine.' (Site from CRA).	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 17:53:26
User opened query 'Per multiple query responses on this page site was unable to reach subject and didn't speak to them on 15Spe2020. Please consider removing all fields noted as NONE and instead click assessment not done box.' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 04:17:54
User entered '0'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '97' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	04 Nov 2020 14:20:48
User entered '90'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User entered '%'	System	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '97.7' F	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User closed query 'Per source, contact was made. If subject did not answer calls and contact was note made, then the assessment should be Not Done.' (Site from CRA).		07 Nov 2020 04:16:46
Query 'Per source, contact was made. If subject did not answer calls and contact was note made, then the assessment should be Not Done.' answered with 'Clarification per previous reply: Contact was made on 15-Sep-2020 but it was documented on the 16-Sep-2020 as information were not reported until late evening. Patient did not have access to their thermometer and O2 machine.' (Site from CRA).	Frances Saubon (b) (4) (b) (4)	04 Nov 2020 19:11:07
User opened query 'Per source, contact was made. If subject did not answer calls and contact was note made, then the assessment should be Not Done.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 17:52:17
User closed query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' (Site from CRA).		04 Nov 2020 17:52:17
Comment added 'Per source at Day 3, dates are fixed and cough and congestion was reported on 16-Sep-2020, not 14-Sep-2020.'	Frances Saubon (b) (4) (b) (4)	04 Nov 2020 14:19:05
Comment added 'Clarification: Contact not made on 15-Sep-2020 however successful contact was made again on 16-Sep-2020. Source will reflect appropriate data changes. Thank you.'	Frances Saubon (b) (4) (b) (4)	03 Nov 2020 20:00:08
Query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' answered with 'Per source, several attempts was made to contact patient but did not answer calls.' (Site from CRA).	Frances Saubon (b) (4) (b) (4)	03 Nov 2020 19:49:33
User opened query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 19:13:28
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User closed query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' (Site from CRA).		07 Nov 2020 04:17:58
Comment added 'Per source at Day 3, dates are fixed and cough and congestion was reported on 16-Sep-2020, not 14-Sep-2020.'	Frances Saubon (b) (4) (b) (4)	04 Nov 2020 14:19:15
Comment added 'Clarification: Contact not made on 15-Sep-2020 however successful contact was made again on 16-Sep-2020. Source will reflect appropriate data changes. Thank you.'	Frances Saubon (b) (4) (b) (4)	03 Nov 2020 20:00:15
Query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' answered with 'Per source, several attempts was made to contact patient but did not answer calls.' (Site from CRA).	Frances Saubon (b) (4) (b) (4)	03 Nov 2020 19:49:37
User opened query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 19:13:33
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:13:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	28 Sep 2020 21:56:59
User entered 'Day 3 (Day 3)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:12:03
User entered '16 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:12:04
User entered '0'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:11:51
User closed query 'Per source, this was corrected to 96%. Please update.' (Site from CRA).	(b) (4)	03 Nov 2020 19:46:05
Query 'Per source, this was corrected to 96%. Please update.' answered with 'updated' (Site from CRA).	Frances Saubon (b) (4)	03 Nov 2020 19:42:18
User entered '96' reason for change: Data Entry Error	(b) (4)	03 Nov 2020 19:42:11
User opened query 'Per source, this was corrected to 96%. Please update.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 19:15:13
User entered '86'	Elisa Moralez (b) (4)	16 Sep 2020 19:14:44
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User entered '%'	System	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:12:01
User entered '98.5' F	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:01:32
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:01:30
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:01:33
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:01:35
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:01:37
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:01:38
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:01:39
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:01:42
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:01:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:01:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:11:24
User closed query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' (Site from CRA).		04 Nov 2020 18:11:22
Query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' answered with 'updated' (Site from CRA).	Frances Saubon (b) (4) (b) (4)	03 Nov 2020 19:42:21
User entered 'Mild (Mild)' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	03 Nov 2020 19:42:11
User opened query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 19:14:49
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:11:26
User closed query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' (Site from CRA).		04 Nov 2020 18:11:25
Query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' answered with 'updated' (Site from CRA).	Frances Saubon (b) (4)	03 Nov 2020 19:42:24
User entered 'Mild (Mild)' reason for change: Per Query Resolution	Frances Saubon (b) (4)	03 Nov 2020 19:42:11
User opened query 'Per source at Day 3, subject reported congestion/runny nose since 14Sep20. Please update.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 19:14:54
User entered 'None (None)'	Elisa Moralez (b) (4)	16 Sep 2020 19:14:44

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:11:40
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:11:42
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:11:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:11:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:14:44

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	28 Sep 2020 21:57:06
User entered 'Day 4 (Day 4)'	Frances Saubon (b) (4)	21 Sep 2020 20:10:11
	(b) (4)	

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:21:28
User entered '17 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:21:30
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per CDM re-query: Previous query text was cut off - it should have read: "It appears that Days 9 and 10 are recorded as 92 % and 93% respectively which is less than or equal to 93%. Please review and make all appropriate updates." (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:27:03
Query 'Per CDM re-query: Previous query text was cut off - it should have read: "It appears that Days 9 and 10 are recorded as 92 % and 93% respectively which is less than or equal to 93%. Please review and make all appropriate updates." answered with 'DAY 9 IN SOURCE IS ACTUALLY LISTED AS "91.9%" BU AS WE CAN ONLY ENTER 2 DIGITS, IT HAS BEEN ROUNDED TO 92. THIS IS ENTERED CORRECTLY. ALSO IN SOURCE, DAY 10 IS ENTERED AS 93.1% BUT AS WE ARE ONLY ALLOWED TO ENTER 2 DIGITS, IT IS ENTERED AS 93. THIS IS CORRECT PER SOURCE' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 15:31:58
User opened query 'Per CDM re-query: Previous query text was cut off - it should have read: "It appears that Days 9 and 10 are recorded as 92 % and 93% respectively which is less than or equal to 93%. Please review and make all appropriate updates." (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 15:22:58
User closed query 'Per CDM: It appears that Days 9 and 10 are recorded as 92 % and 93% respectively which is </=93%. Please review and make all appropriate updates.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 15:22:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Query 'Per CDM: It appears that Days 9 and 10 are recorded as 92 % and 93% respectively which is $\neq 93\%$. Please review and make all appropriate updates.' answered with 'On Day 9, patient had 91.9% O2 saturation. It was rounded and recorded in the field as 92% since the entry field on allowed 2 numerical characters. On Day 10, patient had 93.1% O2 saturation and it was recorded as 93% in the entry field due to the same case. Please advise preferred method of recording.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 18:04:34
User opened query 'Per CDM: It appears that Days 9 and 10 are recorded as 92 % and 93% respectively which is $\neq 93\%$. Please review and make all appropriate updates.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:21:16
DataPoint Verified.		07 Nov 2020 04:18:48
User closed query 'Per source, this was 91.9%. Please confirm.' (Site from CRA).		07 Nov 2020 04:18:40
Query 'Per source, this was 91.9%. Please confirm.' answered with 'Entry box is only allowing to enter 2 numerical digits. Please advise if decimals should be rounded. Thank you.' (Site from CRA).	Frances Saubon (b) (4) (b) (4)	03 Nov 2020 19:47:19
User opened query 'Per source, this was 91.9%. Please confirm.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 19:21:04
User entered '92'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User entered '%'	System	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:49
User entered '98.2' F	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:47
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:21:43
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:43
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:42
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:39
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:37
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:41
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:35
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:23:03
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:43
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:44
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:49
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:51
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:54
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:22:55
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:10:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	28 Sep 2020 21:57:15
User entered 'Day 5 (Day 5)'	Frances Saubon (b) (4)	21 Sep 2020 20:12:26
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:06
User entered '18 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:08
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 04:19:00
User closed query 'Per source, this was 93.1%. Please confirm.' (Site from CRA).	(b) (4)	07 Nov 2020 04:18:57
Query 'Per source, this was 93.1%. Please confirm.' answered with 'Entry box is only allowing to enter 2 numerical digits. Please advise if decimals should be rounded. Thank you.' (Site from CRA).	Frances Saubon (b) (4) (b) (4)	03 Nov 2020 19:47:54
User opened query 'Per source, this was 93.1%. Please confirm.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 19:23:15
User entered '93'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User entered '%'	System	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:32
User entered '98.2' F	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:13
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:11
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:27
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:29
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:33
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:44
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:47
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:49
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:12
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:13
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:23
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:26
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:28
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:12:26

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	28 Sep 2020 21:57:23
User entered 'Day 6 (Day 6)'	Frances Saubon (b) (4)	21 Sep 2020 20:20:53
	(b) (4)	

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:46:32
User entered '19 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:46:33
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 04:19:08
User closed query 'Per source, this was 99.1%. Please confirm.' (Site from CRA).	(b) (4)	07 Nov 2020 04:19:07
Query 'Per source, this was 99.1%. Please confirm.' answered with 'Entry box is only allowing to enter 2 numerical digits. Please advise if decimals should be rounded. Thank you.' (Site from CRA).	Frances Saubon (b) (4) (b) (4)	03 Nov 2020 19:48:04
User opened query 'Per source, this was 99.1%. Please confirm.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 19:27:16
User entered '99'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User entered '%'	System	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:44
User entered '97.2' F	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:46:37
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
DataPoint Verified.	(b) (4)	09 Apr 2021 14:05:23
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
DataPoint Un-verified.	(b) (4)	
	Elisa Moralez (b) (4)	29 Mar 2021 20:56:12
Signature has been broken.	(b) (4)	
	Elisa Moralez (b) (4)	29 Mar 2021 20:56:12
User entered 'Mild (Mild)' reason for change: New Information	(b) (4)	
	Elisa Moralez (b) (4)	29 Mar 2021 20:56:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)' reason for change: New Information	(b) (4)	
	Elisa Moralez (b) (4)	05 Nov 2020 20:28:10
User entered 'Mild (Mild)'	(b) (4)	
	Frances Saubon (b) (4)	21 Sep 2020 20:20:53
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:46:44
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:46:45
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:46:47
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:46:48
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:46:50
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:46:55
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:46:57
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:46:58
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:05
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:08
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:09
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:11
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:30
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:47:31
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:20:53

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	28 Sep 2020 21:57:30
User entered 'Day 7 (Day 7)'	Frances Saubon (b) (4)	21 Sep 2020 20:23:02
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:13
User entered '20 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:15
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '99'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User entered '%'	System	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:58
User entered '97.6' F	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:17
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
DataPoint Verified.	(b) (4)	09 Apr 2021 14:05:31
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
DataPoint Un-verified.	(b) (4)	
	Elisa Moralez (b) (4)	29 Mar 2021 20:56:12
Signature has been broken.	(b) (4)	
	Elisa Moralez (b) (4)	29 Mar 2021 20:56:12
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Elisa Moralez (b) (4)	29 Mar 2021 20:56:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:48:19
User entered 'None (None)'	(b) (4)	
	Frances Saubon (b) (4)	21 Sep 2020 20:23:02
	(b) (4)	

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:20
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:21
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:23
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:34
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:35
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:38
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:39
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:41
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:42
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:44
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:46
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:47
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:48:49
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:23:02

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	28 Sep 2020 21:57:40
User entered 'Day 8 (Day 8)'	(b) (4) Frances Saubon (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered '21 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered '0'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered '99'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User entered '%'	System	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered '98.2' F	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:30:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:24:37

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	28 Sep 2020 21:57:51
User entered 'Day 9 (Day 9)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered '22 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered '97'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User entered '%'	System	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered '98.1' F	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:31:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:49:46

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	28 Sep 2020 21:57:59
User entered 'Day 10 (Day 10)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered '23 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered '94'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User entered '%'	System	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered '98.1' F	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:32:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:51:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	28 Sep 2020 21:58:12
User entered 'Day 11 (Day 11)'	Frances Saubon (b) (4)	24 Sep 2020 21:28:55
	(b) (4)	

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:56:24
User entered '24 Sep 2020'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:56:55
User entered '0'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '99'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User entered '%'	System	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:56:26
User entered '97.1' F	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:56:28
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:56:29
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:56:31
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:56:32
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:56:34
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:56:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:56:37
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:56:39
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:56:40
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:56:42
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:56:51
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:56:50
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:56:48
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:56:47
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:56:45
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:56:44
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:28:55

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	28 Sep 2020 21:58:20
User entered 'Day 12 (Day 12)'	(b) (4) Frances Saubon (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:19
User entered '25 Sep 2020'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:20
User entered '0'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '99'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User entered '%'	System	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:44
User entered '97.7' F	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:45
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:47
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:48
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:50
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:51
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:52
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:54
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:58
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:43:59
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:44:00
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:44:02
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:44:03
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:44:09
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:44:10
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:44:12
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	25 Sep 2020 23:02:00

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Day 18 (Day 18)' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	28 Sep 2020 21:58:35
User entered 'Day 13 (Day 13)'	(b) (4) Frances Saubon (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '26 Sep 2020'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '0'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '96'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User entered '%'	System	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '98.1' F	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'Mild (Mild)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 20:28:43
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:52:23

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Day 19 (Day 19)' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	28 Sep 2020 21:58:43
User entered 'Day 14 (Day 14)'	(b) (4) Frances Saubon (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:45:21
User entered '27 Sep 2020'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:45:29
User entered '0'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '98'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User entered '%'	System	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:45:23
User entered '96.9' F	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:45:31
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:45:33
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:45:34
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:45:36
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:45:37
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:45:38
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:45:40
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint Un-verified.	Elisa Moralez (b) (4)	19 Nov 2020 16:23:03
User entered 'Mild (Mild)' reason for change: New Information	(b) (4) Elisa Moralez (b) (4)	19 Nov 2020 16:23:03
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:45:42
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:45:44
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:45:46
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:45:48
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:45:50
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:45:52
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:45:53
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:45:55
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:45:57
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 20:55:11

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Day 20 (Day 20)' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	28 Sep 2020 21:58:52
User entered 'Day 15 (Day 15)'	(b) (4) Frances Saubon (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered '28 Sep 2020'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered '0'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered '99'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User entered '%'	System	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered '97.3' F	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
DataPoint Un-verified.	Elisa Moralez (b) (4)	19 Nov 2020 16:23:03
User entered 'Mild (Mild)' reason for change: New Information	(b) (4) Elisa Moralez (b) (4)	19 Nov 2020 16:23:03
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:42:01
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	28 Sep 2020 21:03:49

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Day 2 (Day 2)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '10 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '1'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User entered empty.	System	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:47:22

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Day 3 (Day 3)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '11 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '1'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User entered empty.	System	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:28

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Day 4 (Day 4)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '12 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '1'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User entered empty.	System	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:39

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Day 5 (Day 5)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '13 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '1'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User entered empty.	System	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:53:58

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Day 6 (Day 6)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User closed query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 08OCT2020. Please reconcile or clarify.' (Site from DM).		19 Nov 2020 21:26:44
Query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 08OCT2020. Please reconcile or clarify.' answered with 'Per source on Day 15th 28-Sep-2020, all the symptoms are resolved. Please clarify.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 18:17:17
User opened query 'Per CDM: it appears there may be additional symptoms not recorded as there is a Convalescence Visit Day 28 with date of 08OCT2020. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 03:22:49
User entered '14 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '0'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User entered '%'	System	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered '97.2' F	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:14:11

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Dec 2020 00:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	28 Sep 2020 21:56:29

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:11

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 19:59:02
User closed query 'Data is required. Please complete.' (Site from System).		17 Sep 2020 14:47:24
User entered '14 Sep 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:15:31
Query 'Data is required. Please complete.' answered with 'form filled out in error' (Site from System).	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:03:49
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 19:03:46
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:03:46
User entered '14 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:05:50

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:11

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 19:59:02
User closed query 'Data is required. Please complete.' (Site from System).		17 Sep 2020 14:47:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	16 Sep 2020 19:15:31
Query 'Data is required. Please complete.' answered with 'form filled out in error' (Site from System).	(b) (4)	16 Sep 2020 19:03:53
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 19:03:46
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4)	16 Sep 2020 19:03:46
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	15 Sep 2020 20:05:50

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:11

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 19:59:02
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).		21 Sep 2020 06:17:08
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 'Test was positive. Data has been updated on AE form' (Site from System).		18 Sep 2020 23:28:54
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	18 Sep 2020 23:28:18
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	18 Sep 2020 23:28:18
User closed query 'Data is required. Please complete.' (Site from System).		17 Sep 2020 14:47:39
Query 'Data is required. Please complete.' answered with 'TEST RESULTS NOT YET RETURNED' (Site from System).	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:08:19
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 20:05:50
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:05:50

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:11

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 14-SEP-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab 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)	14 Dec 2020 11:06:19
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 14-SEP-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab 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 'PPD is being updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:33:26
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 14-SEP-2020 is recorded under Covid-19 Assessment visit in EDC, however, swab 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)	11 Dec 2020 04:25:09
DataPoint Verified.		02 Nov 2020 19:59:02
User closed query 'Data is required. Please complete.' (Site from System).		17 Sep 2020 14:47:46
User entered '14 Sep 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:15:31
Query 'Data is required. Please complete.' answered with 'form filled out in error' (Site from System).	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:03:57
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 19:03:46
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	16 Sep 2020 19:03:46

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Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:11

[Date of Test](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:05:50

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:11

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:28
DataPoint Verified.		09 Apr 2021 14:04:07
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per GCL Lab Reconciliation: Swab: Per EDC, response to "Other, specify" is entered as "NASOPHARYNGEAL SWAB", however, corresponding option is present in the dropdown. kindly consider selecting the option from the dropdown available on "Type of Test Performed" as appropriate and delete the response from "Other, specify". ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 11:09:58
Query 'Per GCL Lab Reconciliation: Swab: Per EDC, response to "Other, specify" is entered as "NASOPHARYNGEAL SWAB", however, corresponding option is present in the dropdown. kindly consider selecting the option from the dropdown available on "Type of Test Performed" as appropriate and delete the response from "Other, specify". ' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	08 Dec 2020 14:22:36
DataPoint Un-verified.	Frances Saubon (b) (4) (b) (4)	08 Dec 2020 14:22:28
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	08 Dec 2020 14:22:28
User opened query 'Per GCL Lab Reconciliation: Swab: Per EDC, response to "Other, specify" is entered as "NASOPHARYNGEAL SWAB", however, corresponding option is present in the dropdown. kindly consider selecting the option from the dropdown available on "Type of Test Performed" as appropriate and delete the response from "Other, specify". ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 07:32:32
Query 'Per GCL Lab Reconciliation: Swab: Per EDC response to "Other, specify" is entered as "NASOPHARYNGEAL SWAB", however, corresponding option is present in the dropdown. kindly consider selecting the option from the dropdown available on "Type of Test Performed" as appropriate.' canceled (Site from DM).		08 Dec 2020 07:32:26

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Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:11

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:33:51
User entered empty; reason for change Per Query Resolution	Frances Saubon (b) (4)	08 Dec 2020 14:22:28
User closed query ' Per GCL LAB recon: SWAB and Blood: Please confirm the assessment for which the Blood sample was collected on 14Sep2020.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 07:28:13
Query ' Per GCL LAB recon: SWAB and Blood: Please confirm the assessment for which the Blood sample was collected on 14Sep2020.' answered with 'Updated blood was entered in error' (Site from DM).	Blessing Felix-Okoroji (b) (4)	03 Dec 2020 16:16:39
DataPoint Un-verified.	Blessing Felix-Okoroji (b) (4)	03 Dec 2020 16:16:20
User entered 'NASOPHARYNGEAL SWAB' reason for change: Per Query Resolution	Blessing Felix-Okoroji (b) (4)	03 Dec 2020 16:16:20
User opened query ' Per GCL LAB recon: SWAB and Blood: Please confirm the assessment for which the Blood sample was collected on 14Sep2020.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 04:15:27
Query 'Per GCL LAB recon: SWAB and Blood: Please confirm the assessment for which the Blood sample was collected on 21Sep2020. ' canceled (Site from DM).		03 Dec 2020 04:15:12
User opened query 'Per GCL LAB recon: SWAB and Blood: Please confirm the assessment for which the Blood sample was collected on 21Sep2020. ' (Site from DM).		03 Dec 2020 03:55:25
DataPoint Verified.		02 Nov 2020 19:59:02
User entered 'nasopharyngeal swab and blood' reason for change: Data Entry Error	Elisa Moralez (b) (4)	16 Sep 2020 19:15:31
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4)	16 Sep 2020 19:03:46
User entered 'NASOPHARYNGEAL AND BLOOD'	Elisa Moralez (b) (4)	15 Sep 2020 20:05:50

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:11

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 19:59:02
User closed query 'Data is required. Please complete.' (Site from System).		17 Sep 2020 14:47:51
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	16 Sep 2020 19:15:31
Query 'Data is required. Please complete.' answered with 'form filled out in error' (Site from System).	(b) (4)	16 Sep 2020 19:04:03
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 19:03:46
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4)	16 Sep 2020 19:03:46
User entered 'No (N)'	Elisa Moralez (b) (4)	15 Sep 2020 20:05:50

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:11

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 19:59:02
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:05:50

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:11

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 19:59:02
User entered empty.	Elisa Moralez (b) (4) (b) (4)	15 Sep 2020 20:05:50

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:14:11

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:28
User entered '1'	System	18 Sep 2020 23:28:18

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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Folder: Covid-19 Assessment 14 Sep 2020

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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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)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per source, subject reported O2 saturations of 90-93% on 15Sep20, 17-18Sep20. Please update.' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 19:24:28
Comment added 'O2 Saturation for 17-Sep-2020 was 91.9% however entry field only allows 2 numerical digits therefore "91" was recorded.' DataPoint Un-verified.	Frances Saubon (b) (4) (b) (4)	04 Nov 2020 14:34:59
User entered 'Yes (Y)' reason for change: Per Query Resolution	Frances Saubon (b) (4)	04 Nov 2020 14:33:23
Query 'Per source, subject reported O2 saturations of 90-93% on 15Sep20, 17-18Sep20. Please update.' answered with 'Source data has been updated and O2 saturation on the mentioned dates are as follows: 15-Sep-2020, 97%; 16-Sep-2020, 96%; 17-Sep-2020, 91.9%; 18-Sep-2020, 93.1%. O2 saturation for 17-Sep-2020 will be listed in this field as it is ≤ 93%.' (Site from CRA).	Frances Saubon (b) (4) (b) (4)	04 Nov 2020 14:33:23
User opened query 'Per source, subject reported O2 saturations of 90-93% on 15Sep20, 17-18Sep20. Please update.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 14:32:25
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	03 Nov 2020 19:47:32
		02 Nov 2020 20:00:27
		21 Sep 2020 20:36:10

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
DataPoint Verified.	(b) (4)	09 Apr 2021 14:03:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Un-verified.	(b) (4)	
	Frances Saubon (b) (4)	04 Nov 2020 14:33:23
User entered '17 Sep 2020' reason for change: Per Query Resolution	(b) (4)	
	Frances Saubon (b) (4)	04 Nov 2020 14:33:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:35:59
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:17:57
User closed query 'Per CDM : Please note as per the Symptom log day 10 (18-Sep20) has a O2 saturation of 93%.Kindly correct the end date in the severity assessment or clarify.Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 16:35:59
Query 'Per CDM : Please note as per the Symptom log day 10 (18-Sep20) has a O2 saturation of 93%.Kindly correct the end date in the severity assessment or clarify.Thanks ' answered with 'updated, thank you!!' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 14:19:37
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 14:19:20
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 14:19:20
User entered '18 Sep 2020' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 14:19:20
User opened query 'Per CDM : Please note as per the Symptom log day 10 (18-Sep20) has a O2 saturation of 93%.Kindly correct the end date in the severity assessment or clarify.Thanks ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 12:03:34
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:03:48
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 01:54:59
Query 'Please verify as symptom log notes last day < /= 93% was on 18Sep2020' canceled (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 19:24:52
User opened query 'Please verify as symptom log notes last day < /= 93% was on 18Sep2020' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 04:20:56
DataPoint Un-verified.	Frances Saubon (b) (4) (b) (4)	04 Nov 2020 14:33:23
User entered '17 Sep 2020' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	04 Nov 2020 14:33:23
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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Folder: Covid-19 Assessment 14 Sep 2020

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 13:36:01
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:17:57
User closed query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:15:18
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' answered with 'So sorry, the previous response was one for a different query. The information present in this folder is accurate per source and symptom log review. Thank you.' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	22 Apr 2021 16:41:15
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 16:38:25
User closed query 'Per CDM :Please note the O2 saturation lowest in the symptom log is 92% in severity assessment form it is 91%, kindly reconcile and correct accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 16:38:25
Query 'Per CDM :Please note the O2 saturation lowest in the symptom log is 92% in severity assessment form it is 91%, kindly reconcile and correct accordingly.' answered with 'Day 5 sample was collected on March 5th and shipped on March 9th. Result pending' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 14:19:29
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 14:19:20
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 14:19:20
User entered '92' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	21 Apr 2021 14:19:20

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Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
User opened query 'Per CDM :Please note the O2 saturation lowest in the symptom log is 92% in severity assessment form it is 91%, kindly reconcile and correct accordingly.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 12:03:10
User signature succeeded.	(b) (4)	09 Apr 2021 14:03:47
DataPoint Un-verified.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '91' reason for change: Per Query Resolution DataPoint Verified.	(b) (4)	(b) (4)
User entered empty.	Frances Saubon (b) (4)	04 Nov 2020 14:33:23
	(b) (4)	(b) (4)
	Frances Saubon (b) (4)	04 Nov 2020 14:33:23
	(b) (4)	(b) (4)
	(b) (4), (b) (6)	02 Nov 2020 20:00:27
	(b) (4)	(b) (4)
	Frances Saubon (b) (4)	21 Sep 2020 20:36:10
	(b) (4)	(b) (4)

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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Folder: Covid-19 Assessment 14 Sep 2020

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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[Start Date](#)

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Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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[Evidence of Shock Requires Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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[Start Date](#)

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Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

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[End Date](#)

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Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:14:11

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:00:27
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 20:36:10

US3322006

Folder: Covid-19 Assessment 14 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:14:11

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:33:40
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:04:02
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	16 Sep 2020 19:04:19
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	16 Sep 2020 18:19:07

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:14:11

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
User accepted default value 'Day 3 (Day 3)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:09:50

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:14:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:39:10
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:09:50

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:14:11

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:39:10
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16,18,21,23,28SEP2020 and 05,08OCT2020 is recorded under Illness Visit Day 3-21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		09 Dec 2020 09:07:15
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16,18,21,23,28SEP2020 and 05,08OCT2020 is recorded under Illness Visit Day 3-21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Accession number now being updated in PPD logs.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 16:31:58
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16,18,21,23,28SEP2020 and 05,08OCT2020 is recorded under Illness Visit Day 3-21 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:11:17
User entered '16 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:09:50

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:14:11

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
User accepted default value 'Day 5 (Day 5)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:10:35

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:14:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:39:10
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:10:35

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:14:11

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:39:10
User entered '18 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:10:35

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:14:11

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
User accepted default value 'Day 7 (Day 7)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:11:04

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:14:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:39:10
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:11:04

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:14:11

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:39:10
User entered '21 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:11:04

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:14:11

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
User accepted default value 'Day 9 (Day 9)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:30:42

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:14:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:39:10
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:30:42

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:14:11

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:39:10
User entered '23 Sep 2020'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:30:42

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:14:11

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
User accepted default value 'Day 14 (Day 14)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:30:42

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:14:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:39:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Frances Saubon (b) (4)	28 Sep 2020 21:19:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	25 Sep 2020 09:18:57
Query 'Data is required. Please complete.' answered with 'Day 14 has not been completed yet, will enter once completed' (Site from System).	Frances Saubon (b) (4)	24 Sep 2020 21:31:08
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 21:30:42
User entered empty.	Frances Saubon (b) (4)	24 Sep 2020 21:30:42

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:14:11

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:39:10
User entered '28 Sep 2020' reason for change: Data Entry Error	Frances Saubon (b) (4)	28 Sep 2020 21:19:16
User entered empty.	(b) (4) Frances Saubon (b) (4)	24 Sep 2020 21:30:42

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:14:11

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
User accepted default value 'Day 21 (Day 21)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:30:42

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:14:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:39:10
User entered 'Yes (Y)' reason for change: New Information	Elisa Moralez (b) (4)	21 Oct 2020 15:24:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Sep 2020 09:18:59
Query 'Data is required. Please complete.' answered with 'Day 21 has not been completed yet, will enter once completed' (Site from System).	Frances Saubon (b) (4)	24 Sep 2020 21:31:14
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 21:30:42
User entered empty.	Frances Saubon (b) (4)	24 Sep 2020 21:30:42

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:14:11

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
DataPoint Verified.		02 Mar 2021 16:11:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per GCL LAB reconciliation Requery: Saliva: Per response "PPD is being updated". Data is present in PDD however the date of collection is missing in PPD. Please review the Preclarus and update the missing date of collection in Preclarus. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 11:39:14
Query 'Per GCL LAB reconciliation Requery: Saliva: Per response "PPD is being updated". Data is present in PDD however the date of collection is missing in PPD. Please review the Preclarus and update the missing date of collection in Preclarus. Thank you.' answered with 'time collected was 12:00 on 05-Oct-2020, date received on site was 06-Oct-2020, ' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 14:39:34
User opened query 'Per GCL LAB reconciliation Requery: Saliva: Per response "PPD is being updated". Data is present in PDD however the date of collection is missing in PPD. Please review the Preclarus and update the missing date of collection in Preclarus. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 05:53:07
User closed query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 05OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).		18 Jan 2021 05:53:07
Query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 05OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'PPD is being updated, sample has shipped, this was over 2 months ago' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	11 Jan 2021 15:42:29
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	11 Jan 2021 15:42:04

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:14:11

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020' reason for change: New Information	Elisa Moralez (b) (4)	11 Jan 2021 15:42:04
User opened query 'Per GCL LAB reconciliation: Saliva: Day 21 sample dated 05OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Jan 2021 10:05:22
	(b) (4), (b) (6)	15 Dec 2020 21:39:10
User entered '5 Oct 2020' reason for change: New Information	Elisa Moralez (b) (4)	05 Nov 2020 20:33:35
User entered '6 Oct 2020' reason for change: New Information	(b) (4)	
	Elisa Moralez (b) (4)	21 Oct 2020 15:24:21
User entered empty.	(b) (4)	
	Frances Saubon (b) (4)	24 Sep 2020 21:30:42
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:14:11

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
User accepted default value 'Day 28 (Day 28)'	Frances Saubon (b) (4) (b) (4)	24 Sep 2020 21:30:42

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:14:11

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:39:10
User entered 'Yes (Y)' reason for change: New Information	Elisa Moralez (b) (4)	21 Oct 2020 15:24:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Sep 2020 09:19:02
Query 'Data is required. Please complete.' answered with 'Day 28 has not been completed yet, will enter once completed' (Site from System).	Frances Saubon (b) (4)	24 Sep 2020 21:31:21
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 21:30:42
User entered empty.	Frances Saubon (b) (4)	24 Sep 2020 21:30:42

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:14:11

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:53
DataPoint Verified.		02 Mar 2021 16:09:18
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number and tracking number in query response for tracking purpose.' (Site from DM). User signature succeeded.		26 Feb 2021 10:05:15
	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number and tracking number in query response for tracking purpose.' answered with '1F69182' (Site from DM).	Elisa Moralez (b) (4)	25 Jan 2021 18:24:03
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the accession number and tracking number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:02:04
User closed query 'Per GCL LAB reconciliation: Saliva: Day 28 sample dated 08OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD.' (Site from DM).		25 Jan 2021 07:02:04
Query 'Per GCL LAB reconciliation: Saliva: Day 28 sample dated 08OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD.' answered with 'sample is updated' (Site from DM).	Elisa Moralez (b) (4)	11 Jan 2021 15:42:47
	(b) (4)	
DataPoint Un-verified.	Elisa Moralez (b) (4)	11 Jan 2021 15:42:35
	(b) (4)	
User entered '08 Oct 2020' reason for change: New Information	Elisa Moralez (b) (4)	11 Jan 2021 15:42:35
	(b) (4)	

US3322006

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:14:11

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: Day 28 sample dated 08OCT2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	10 Jan 2021 10:06:09
	(b) (4), (b) (6)	15 Dec 2020 21:39:10
User entered '8 Oct 2020' reason for change: New Information	Elisa Moralez (b) (4)	21 Oct 2020 15:24:38
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	24 Sep 2020 21:30:42
	(b) (4)	

US3322006

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:07:44
User entered 'Yes (Y)'		18 Sep 2020 23:29:31

US3322006

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:07:44
User entered '14 Sep 2020'		18 Sep 2020 23:29:31

US3322006

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[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 14:12:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:07:44
User entered 'Clinic (Clinic)'		18 Sep 2020 23:29:31

US3322006

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:44
User entered 'SICKD1'	System	18 Sep 2020 23:29:31

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:11:39
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:11:41
User entered '14 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 17:48:32
User closed query 'Per source, it states that the time of assessment is 14:15 vs 14:30. Please confirm and update accordingly.' (Site from CRA).		04 Nov 2020 17:48:30
Query 'Per source, it states that the time of assessment is 14:15 vs 14:30. Please confirm and update accordingly.' answered with 'updated' (Site from CRA).	Frances Saubon (b) (4) (b) (4)	02 Nov 2020 21:19:48
User entered '14:15' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	02 Nov 2020 21:19:42
User opened query 'Per source, it states that the time of assessment is 14:15 vs 14:30. Please confirm and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 20:11:35
User entered '14:30'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:55
User entered '14 Sep 2020 14:15'	System	02 Nov 2020 21:19:42
User entered '14 Sep 2020 14:30'	System	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:11:43
User entered '67' in	Frances Saubon (b) (4)	21 Sep 2020 19:07:42
DataPoint set to visible.	(b) (4) System	18 Sep 2020 23:29:31

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:11:45
User entered '256.6' lb	Frances Saubon (b) (4)	21 Sep 2020 19:07:42
DataPoint set to visible.	(b) (4) System	18 Sep 2020 23:29:31

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:11:46
User entered '97.2' F	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:11:50
User entered 'Oral (Oral)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:11:52
User entered empty.	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:11:54
User entered '91'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:55
User entered 'bpm'	System	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:11:55
User entered '18'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:55
User entered 'breaths/min'	System	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:11:58
User closed query 'Per ETRTR: Please confirm clinical significance on high blood pressure and consider reporting if applicable, thanks.' (Site from CRA).		30 Oct 2020 03:55:00
Query 'Per ETRTR: Please confirm clinical significance on high blood pressure and consider reporting if applicable, thanks.' answered with 'ncs' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 14:34:17
User opened query 'Per ETRTR: Please confirm clinical significance on high blood pressure and consider reporting if applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 14:30:16
User entered '132'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:55
User entered 'mmHg'	System	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:12:02
User entered '95'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:55
User entered 'mmHg'	System	21 Sep 2020 19:07:42

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:55

US3322006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:12:55

US3322006

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:12:11
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:08:02

US3322006

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:12:11
User entered '14 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:08:02

US3322006

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:14:11

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:12:37
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:08:30

US3322006

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:14:11

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:12:37
User entered '14 Sep 2020'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 19:08:30

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:38:13
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:17:52

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:16
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 08-OCT-2020 is recorded under Convalescence Visit Day 28 in PPD portal; however, swab sample for 08-OCT-2020 is missing in EDC. Kindly consider initiating separate Covid-19 Assessment eCRF for 08-OCT-2020 and update swab data in COVID Diagnostic Test eCRF as there is no provision to capture swab data in convalescence eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 12:48:04
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 08-OCT-2020 is recorded under Convalescence Visit Day 28 in PPD portal; however, swab sample for 08-OCT-2020 is missing in EDC. Kindly consider initiating separate Covid-19 Assessment eCRF for 08-OCT-2020 and update swab data in COVID Diagnostic Test eCRF as there is no provision to capture swab data in convalescence eCRF, else clarify.' answered with 'saliva collection is entered under Saliva Collection page, day 28, per eCRF guidelines' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	22 Mar 2021 20:46:13
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 08-OCT-2020 is recorded under Convalescence Visit Day 28 in PPD portal; however, swab sample for 08-OCT-2020 is missing in EDC. Kindly consider initiating separate Covid-19 Assessment eCRF for 08-OCT-2020 and update swab data in COVID Diagnostic Test eCRF as there is no provision to capture swab data in convalescence eCRF, else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 06:23:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:38:13
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).' ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 17:13:36

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). ' answered with 'Corrected' (Site from DM).	Frances Saubon (b) (4) (b) (4)	30 Oct 2020 15:49:43
User entered '08 Oct 2020' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	30 Oct 2020 15:49:22
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 15:42:23
User entered '8 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:17:52

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[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 14:13:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:38:13
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:17:52

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:16
User entered 'SICKD28'	System	21 Oct 2020 13:17:52

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:38:29
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:38:29
User closed query 'Per CDM: Please consider updating the Date format to DD-MMM-YYYY including 2 digits for the day (for example 01-JAN-1999). ' (Site from DM).		10 Nov 2020 17:42:47
Query 'Per CDM: Please consider updating the Date format to DD-MMM-YYYY including 2 digits for the day (for example 01-JAN-1999). ' answered with 'Date updated per query' (Site from DM).	Blessing Felix-Okoroji (b) (4)	09 Nov 2020 19:57:14
User entered '08 Oct 2020' reason for change: Per Query Resolution	Blessing Felix-Okoroji (b) (4)	09 Nov 2020 19:57:05
User opened query 'Per CDM: Please consider updating the Date format to DD-MMM-YYYY including 2 digits for the day (for example 01-JAN-1999). ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:10:17
User entered '8 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:38:29
User entered '13:30'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:21
User entered '08 Oct 2020 13:30'	System	09 Nov 2020 19:57:05
User entered '8 Oct 2020 13:30'	System	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:38:29
User entered '67' in	Elisa Moralez (b) (4)	21 Oct 2020 13:18:47
DataPoint set to visible.	(b) (4) System	21 Oct 2020 13:17:52

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:38:29
User entered '255' lb	Elisa Moralez (b) (4)	21 Oct 2020 13:18:47
DataPoint set to visible.	(b) (4) System	21 Oct 2020 13:17:52

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:38:29
User entered '97.9' F	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:38:29
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:38:29
User entered empty.	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:38:29
User entered '69'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:21
User entered 'bpm'	System	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:38:29
User entered '17'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:21
User entered 'breaths/min'	System	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:38:29
User entered '150'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:21
User entered 'mmHg'	System	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:38:29
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		22 Oct 2020 07:08:11
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:58
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		21 Oct 2020 13:18:47
User entered '104'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:21
User entered 'mmHg'	System	21 Oct 2020 13:18:47

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:21

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:21

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:38:48
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:19:12

US3322006

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:38:48
User entered '8 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:19:12

US3322006

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:14:11

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:38:59
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re- Query: Thank you for the response, Please confirm the correct visit label in the response for the SARS-CoV-2 serum sample dated 08 OCT 2020 as it is recorded under Convalescence Visit Day 28 in EDC and UNSCHEDULED visit in PPD Central lab.' (Site from DM).		08 Dec 2020 10:23:16
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re- Query: Thank you for the response, Please confirm the correct visit label in the response for the SARS-CoV-2 serum sample dated 08 OCT 2020 as it is recorded under Convalescence Visit Day 28 in EDC and UNSCHEDULED visit in PPD Central lab.' answered with 'This sample is for Convalescence Visit Day 28 on 08-Oct-2020. ' (Site from DM).	Frances Saubon (b) (4) (b) (4)	04 Dec 2020 16:20:10
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re- Query: Thank you for the response, Please confirm the correct visit label in the response for the SARS-CoV-2 serum sample dated 08 OCT 2020 as it is recorded under Convalescence Visit Day 28 in EDC and UNSCHEDULED visit in PPD Central lab.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 07:44:07
User closed query 'Per GCL Lab Reconciliation: SARS Cov2: Sample dated 08OCT2020 is recorded under Convalescence visit Day 28 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:36:44

US3322006

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:14:11

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS Cov2: Sample dated 08OCT2020 is recorded under Convalescence visit Day 28 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' answered with 'Please note that a DCF has been submitted. Thank you.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 13:35:29
User opened query 'Per GCL Lab Reconciliation: SARS Cov2: Sample dated 08OCT2020 is recorded under Convalescence visit Day 28 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:15:02
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	21 Oct 2020 13:19:21

US3322006

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:14:11

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:13:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:38:59
User entered '08 Oct 2020' reason for change: Data Entry Error	Frances Saubon (b) (4)	04 Dec 2020 16:20:17
User entered '8 Oct 2020'	Elisa Moralez (b) (4)	21 Oct 2020 13:19:21

US3322006

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

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	23 Jan 2021 21:51:00

US3322006

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

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '23 Jan 2021'	Elisa Moralez (b) (4)	23 Jan 2021 21:51:00

US3322006

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

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4)	23 Jan 2021 21:51:00

US3322006

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

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'UNBLND_DECIDE'	System	23 Jan 2021 21:51:00

US3322006

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

Form: Unblinding

Generated On: 11 Aug 2021 22:14:11

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '23 Jan 2021'	Elisa Moralez (b) (4)	23 Jan 2021 21:51:41

US3322006

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

Form: Unblinding

Generated On: 11 Aug 2021 22:14:11

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:08:34

US3322006

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

Form: Unblinding

Generated On: 11 Aug 2021 22:14:11

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	23 Jan 2021 21:51:41

US3322006

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

Form: Unblinding

Generated On: 11 Aug 2021 22:14:11

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:08:34

US3322006

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

Form: Unblinding

Generated On: 11 Aug 2021 22:14:11

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '23 Jan 2021'	Elisa Moralez (b) (4)	23 Jan 2021 21:51:41

US3322006

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

Form: Unblinding

Generated On: 11 Aug 2021 22:14:11

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Placebo (Placebo)'	Elisa Moralez (b) (4)	23 Jan 2021 21:51:41

US3322006

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

Form: Unblinding

Generated On: 11 Aug 2021 22:14:11

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Placebo (Placebo)'	Elisa Moralez (b) (4)	23 Jan 2021 21:51:41

US3322006

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

Form: Unblinding

Generated On: 11 Aug 2021 22:14:11

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Placebo (Placebo)'	Elisa Moralez (b) (4)	23 Jan 2021 21:51:41

US3322006

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

Form: Unblinding

Generated On: 11 Aug 2021 22:14:11

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	23 Jan 2021 21:51:41

US3322006

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

Form: Unblinding

Generated On: 11 Aug 2021 22:14:11

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered '1'	System	23 Jan 2021 21:51:41

US3322006

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

Form: Unblinding

Generated On: 11 Aug 2021 22:14:11

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered '1'	System	23 Jan 2021 21:51:41

US3322006

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered empty.	System	23 Jan 2021 21:52:42
DataPoint set to visible.	System	23 Jan 2021 21:51:41

US3322006

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered empty.	System	23 Jan 2021 21:52:42
DataPoint set to visible.	System	23 Jan 2021 21:51:41

US3322006

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User accepted default value 'Pre-Dose (PREDOSE)'	Elisa Moralez (b) (4) (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '23 Jan 2021'	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '13:11'	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered '23 Jan 2021 13:11'	System	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '98.4' F	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Oral (Oral)'	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '75'	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'bpm'	System	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '17'	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'breaths/min'	System	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '135'	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'mmHg'	System	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '90'	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'mmHg'	System	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:14:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered empty.	System	23 Jan 2021 21:52:42
DataPoint set to visible.	System	23 Jan 2021 21:51:41

US3322006

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User accepted default value 'Post-Dose (POSTDOSE)'	Elisa Moralez (b) (4) (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '23 Jan 2021'	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '15:45'	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered '23 Jan 2021 15:45'	System	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '98.4' F	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Oral (Oral)'	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '74'	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'bpm'	System	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '16'	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'breaths/min'	System	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '130'	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'mmHg'	System	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '86'	Elisa Moralez (b) (4)	23 Jan 2021 21:52:42

US3322006

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'mmHg'	System	23 Jan 2021 21:52:42

US3322006

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4)	23 Jan 2021 21:53:22

US3322006

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '23 Jan 2021'	Elisa Moralez (b) (4)	23 Jan 2021 21:53:22

US3322006

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

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	23 Jan 2021 21:53:34

US3322006

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

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	23 Jan 2021 21:53:34

US3322006

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

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	23 Jan 2021 21:53:34

US3322006

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

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'mRNA-1273'	System	23 Jan 2021 21:53:34
DataPoint set to visible.	System	23 Jan 2021 21:51:41

US3322006

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

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '23 Jan 2021'	Elisa Moralez (b) (4)	23 Jan 2021 21:53:34

US3322006

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

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '14:58'	Elisa Moralez (b) (4)	23 Jan 2021 21:53:34

US3322006

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

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered '23 Jan 2021 14:58'	System	23 Jan 2021 21:53:34

US3322006

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

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Left Arm (LEFT ARM)'	Elisa Moralez (b) (4)	23 Jan 2021 21:53:34

US3322006

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

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'ONCE'	System	23 Jan 2021 21:53:34

US3322006

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

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'INTRAMUSCULAR'	System	23 Jan 2021 21:53:34

US3322006

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4)	23 Jan 2021 21:53:42

US3322006

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '23 Jan 2021'	Elisa Moralez (b) (4)	23 Jan 2021 21:53:42

US3322006

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '14:25'	Elisa Moralez (b) (4)	23 Jan 2021 21:53:42

US3322006

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered '23 Jan 2021 14:25'	System	23 Jan 2021 21:53:42

US3322006

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:14:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	23 Jan 2021 21:53:48

US3322006

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:14:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '23 Jan 2021'	Elisa Moralez (b) (4)	23 Jan 2021 21:53:48

US3322006

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:14:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '14:20'	Elisa Moralez (b) (4)	23 Jan 2021 21:53:48

US3322006

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered '23 Jan 2021 14:20'	System	23 Jan 2021 21:53:48

US3322006

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

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	23 Jan 2021 21:53:51

US3322006

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

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered '1'	System	23 Jan 2021 21:53:51

US3322006

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	03 Feb 2021 19:55:32

US3322006

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '02 Feb 2021'	Elisa Moralez (b) (4)	03 Feb 2021 19:55:32

US3322006

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	03 Feb 2021 19:55:32

US3322006

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	03 Feb 2021 19:55:32

US3322006

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	03 Feb 2021 19:55:38

US3322006

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered '1'	System	03 Feb 2021 19:55:38

US3322006

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered '1'	System	03 Feb 2021 19:55:38
DataPoint set to visible.	System	03 Feb 2021 19:55:38

US3322006

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	23 Feb 2021 22:16:00

US3322006

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '23 Feb 2021'	Elisa Moralez (b) (4)	23 Feb 2021 22:16:00

US3322006

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4)	23 Feb 2021 22:16:00

US3322006

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'OLD29'	System	23 Feb 2021 22:16:00

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User accepted default value 'Pre-Dose (PREDOSE)'	Elisa Moralez (b) (4) (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '23 Feb 2021'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '14:09'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered '23 Feb 2021 14:09'	System	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '97.1' F	Elisa Moralez (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Oral (Oral)'	(b) (4) Elisa Moralez (b) (4)	23 Feb 2021 22:17:06
	(b) (4)	

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '84'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'bpm'	System	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '13'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'breaths/min'	System	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '139'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'mmHg'	System	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '91'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:14:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'mmHg'	System	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User accepted default value 'Post-Dose (POSTDOSE)'	Elisa Moralez (b) (4) (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '23 Feb 2021'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '15:45'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered '23 Feb 2021 15:45'	System	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '96.9' F	Elisa Moralez (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Oral (Oral)'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '77'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'bpm'	System	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '13'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'breaths/min'	System	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '136'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'mmHg'	System	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '96'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'mmHg'	System	23 Feb 2021 22:17:06

US3322006

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:17

US3322006

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '23 Feb 2021'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:17

US3322006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:32

US3322006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	23 Feb 2021 22:17:32

US3322006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	23 Feb 2021 22:17:32

US3322006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'mRNA-1273'	System	23 Feb 2021 22:17:32
DataPoint set to visible.	System	03 Feb 2021 19:55:38

US3322006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '23 Feb 2021'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:32

US3322006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '15:09'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:32

US3322006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered '23 Feb 2021 15:09'	System	23 Feb 2021 22:17:32

US3322006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Left Arm (LEFT ARM)'	Elisa Moralez (b) (4)	23 Feb 2021 22:17:32

US3322006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'ONCE'	System	23 Feb 2021 22:17:32

US3322006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'INTRAMUSCULAR'	System	23 Feb 2021 22:17:32

US3322006

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	23 Feb 2021 22:17:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Feb 2021 22:17:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	23 Feb 2021 22:17:44
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Feb 2021 22:17:41
User entered empty.	Elisa Moralez (b) (4) (b) (4)	23 Feb 2021 22:17:41

US3322006

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered '1'	System	23 Feb 2021 22:17:44
User entered empty.	System	23 Feb 2021 22:17:41

US3322006

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	16 Mar 2021 18:29:42

US3322006

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered '03 Mar 2021'	Elisa Moralez (b) (4)	16 Mar 2021 18:29:42

US3322006

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	16 Mar 2021 18:29:42

US3322006

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:14:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered empty.	Elisa Moralez (b) (4)	16 Mar 2021 18:29:42

US3322006

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	16 Mar 2021 18:29:46

US3322006

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:14:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered '1'	System	16 Mar 2021 18:29:46

US3322006

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	24 Mar 2021 19:46:49

US3322006

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered '24 Mar 2021'	Elisa Moralez (b) (4)	24 Mar 2021 19:46:49

US3322006

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4)	24 Mar 2021 19:46:49

US3322006

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:14:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered 'OLD57'	System	24 Mar 2021 19:46:49

US3322006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered 'No (N)'	Elisa Moralez (b) (4)	24 Mar 2021 19:46:56

US3322006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered empty.	Elisa Moralez (b) (4)	24 Mar 2021 19:46:56

US3322006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered empty.	Elisa Moralez (b) (4)	24 Mar 2021 19:46:56

US3322006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered empty.	System	24 Mar 2021 19:46:56

US3322006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered empty.	Elisa Moralez (b) (4)	24 Mar 2021 19:46:56

US3322006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered empty.	Elisa Moralez (b) (4)	24 Mar 2021 19:46:56

US3322006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered empty.	(b) (4) Elisa Moralez (b) (4)	24 Mar 2021 19:46:56

US3322006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered empty.	Elisa Moralez (b) (4)	24 Mar 2021 19:46:56

US3322006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered empty.	System	24 Mar 2021 19:46:56

US3322006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered empty.	Elisa Moralez (b) (4)	24 Mar 2021 19:46:56

US3322006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered empty.	System	24 Mar 2021 19:46:56

US3322006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered empty.	Elisa Moralez (b) (4)	24 Mar 2021 19:46:56

US3322006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered empty.	System	24 Mar 2021 19:46:56

US3322006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered empty.	Elisa Moralez (b) (4)	24 Mar 2021 19:46:56

US3322006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered empty.	System	24 Mar 2021 19:46:56

US3322006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45

US3322006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:14:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45

US3322006

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered 'No (N)'	Elisa Moralez (b) (4)	24 Mar 2021 19:46:58

US3322006

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:14:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered empty.	Elisa Moralez (b) (4)	24 Mar 2021 19:46:58

US3322006

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	24 Mar 2021 19:51:10

US3322006

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered '24 Mar 2021'	Elisa Moralez (b) (4)	24 Mar 2021 19:51:10

US3322006

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered '11:52'	Elisa Moralez (b) (4)	24 Mar 2021 19:51:10

US3322006

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:14:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:25:45
User entered '24 Mar 2021 11:52'	System	24 Mar 2021 19:51:10

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:14:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:06
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 19:00:08
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	17 Aug 2020 18:42:14

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	10 Feb 2021 18:57:14
Reviewed for Safety.		20 Sep 2020 18:19:42
User entered 'USA-US060-2020-mRNA-1273-P301000003'		20 Sep 2020 18:19:37
User entered 'New'		20 Sep 2020 18:19:37

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User coded data point as SOC: Infections and infestations, HLG: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 12:51:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 12:51:52
Data point term sent to Coder	System	29 Sep 2020 19:13:04
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 19:12:48
User entered 'Symptomatic Covid -19' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	29 Sep 2020 19:12:48
User closed query 'PV Query: Please consider updating event term to COVID-19 infection, as diagnosis was confirmed by both diagnostic test results and the subject's clinical presentation.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 16:42:51
User coded data point as SOC: Infections and infestations, HLG: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 20:26:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 20:26:47
Data point term sent to Coder	System	28 Sep 2020 20:25:24
Query 'PV Query: Please consider updating event term to COVID-19 infection, as diagnosis was confirmed by both diagnostic test results and the subject's clinical presentation.' answered with 'data updated' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 20:25:21
Coding entries removed.		28 Sep 2020 20:25:14
User entered 'COVID-19 infection' reason for change: Data Entry Error		28 Sep 2020 20:25:14
User opened query 'PV Query: Please consider updating event term to COVID-19 infection, as diagnosis was confirmed by both diagnostic test results and the subject's clinical presentation.' (Site from Safety).		25 Sep 2020 17:17:24

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLG: Microbiology and serology investigations, HLT: Virus identification and serology, PT: SARS-CoV-2 test positive, LLT: COVID-19 virus test positive - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 05:15:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 05:15:47
Data point term sent to Coder	System	18 Sep 2020 23:27:34
User entered 'Confirmed, positive COVID-19 case'	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	10 Feb 2021 18:57:14
User entered 'Yes (Y)'		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	10 Feb 2021 18:57:14
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE is not a solicited event. Please review and update accordingly. Otherwise, clarify.' (Site from DM).		21 Oct 2020 14:38:47
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE is not a solicited event. Please review and update accordingly. Otherwise, clarify.' answered with 'UPDATED. THIS IS NOT A SOLICITED ADVERSE REACTION' (Site from DM).	Blessing Felix-Okoroji (b) (4)	20 Oct 2020 14:42:06
User entered 'No (N)' reason for change: Data Entry Error	Blessing Felix-Okoroji (b) (4)	20 Oct 2020 14:41:45
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE is not a solicited event. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 06:13:04
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE is not a solicited event. Please review and update accordingly. Otherwise, clarify.' canceled (Site from DM).		20 Oct 2020 06:03:52
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE is not a solicited event. Please review and update accordingly. Otherwise, clarify.' (Site from DM).		20 Oct 2020 06:03:50
User entered 'Yes (Y)'		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User entered 'Yes (Y)'		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User entered '09 Sep 2020'		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User entered empty.		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User entered 'No (N)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:02:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
Signature has been broken.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:06:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:47:47
User closed query 'Per source end date is noted as 20Sep20. Please confirm with source and update accordingly.' (Site from CRA).		11 Feb 2021 14:47:43
Query 'Per source end date is noted as 20Sep20. Please confirm with source and update accordingly.' answered with 'confirmed, this is the correct date, data has been corrected in EDC to reflect that' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	10 Feb 2021 21:23:01
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	10 Feb 2021 21:22:25
User entered '20 Sep 2020' reason for change: New Information	Elisa Moralez (b) (4)	10 Feb 2021 21:22:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User opened query 'Per source end date is noted as 20Sep20. Please confirm with source and update accordingly.' (Site from CRA).		10 Feb 2021 18:56:33
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).		07 Oct 2020 15:23:23
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	06 Oct 2020 19:02:38
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	06 Oct 2020 19:02:38
User entered '6 Oct 2020' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:02:38
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	06 Oct 2020 19:02:19

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

If not Ongoing, end date (dd MMM yyyy)

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' answered with 'Noted, this field will be updated once end date is available. Thank you.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	06 Oct 2020 13:17:28
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)	05 Oct 2020 19:08:52
User entered empty.		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
Signature has been broken.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:06:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User entered empty.		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[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)	29 Sep 2020 21:50:20
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)	25 Sep 2020 17:16:16
User entered empty.	System	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User entered 'Grade 2/Moderate (Grade 2/Moderate)'		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User entered 'No (N)'		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

Death

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User entered '0'		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User entered '0'		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User entered '0'		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
Signature has been broken.	(b) (4) (u) (4), (b) (6)	26 Mar 2021 20:06:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	10 Feb 2021 18:57:14
User entered empty.		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
Signature has been broken.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:07:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User entered empty.		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
Signature has been broken.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:07:07
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User entered empty.		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
Signature has been broken.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:07:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User entered empty.		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	10 Feb 2021 18:57:14
User entered '0'		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User entered '0'		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User entered '0'		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).		25 Sep 2020 13:22:56
Comment added 'Entry is correct, subject discontinued from treatment due to COVID-19 positive test per sponsor instructions. This is not related to IP.'	Frances Saubon (b) (4) (b) (4)	21 Sep 2020 16:07:37
User opened query 'Action taken with investigational System product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).		18 Sep 2020 23:27:16
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User entered 'Not Related (NOT RELATED)'		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	10 Feb 2021 18:57:14
User closed query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' (Site from DM).		24 Sep 2020 06:59:28
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		24 Sep 2020 06:53:57
Query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' answered with 'will finish final forms upon completion of all followup illness telehealth visits' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:47:40
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'covid positive test is reason for dosing discontinuation' (Site from System).	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:47:20
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	23 Sep 2020 20:46:31
User opened query 'Per CDM: Since subject withdrawn from the study, then please kindly consider completing "End of Study" forms. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 11:55:14
User entered 'Investigational Product Withdrawn (WITHDRAWN)'		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

None

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:24:34
Signature has been broken.	(b) (4) Elisa Moralez (b) (4)	05 Apr 2021 20:08:42
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
Signature has been broken.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:06:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User entered '0'		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
Signature has been broken.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:06:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User closed query 'PEr CDM: "Concomitant Medication" has been added for this AE, however there is no Medication with the Indication of "symptomatic Covid 19". Please review and update or update accordingly. ' (Site from DM).		23 Oct 2020 14:21:54
Query 'PEr CDM: "Concomitant Medication" has been added for this AE, however there is no Medication with the Indication of "symptomatic Covid 19". Please review and update or update accordingly. ' answered with 'will update per updated source immediately, thank you' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:37:43
User opened query 'PEr CDM: "Concomitant Medication" has been added for this AE, however there is no Medication with the Indication of "symptomatic Covid 19". Please review and update or update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:10:46
User entered '1'		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	31 Mar 2021 23:42:10
Signature has been broken.	(b) (4) (D) (4), (b) (6)	26 Mar 2021 20:06:27
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	10 Feb 2021 18:57:14
User entered '0'		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		07 Oct 2020 15:23:29
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'data updated today in source, promptly entered here, thank you!' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:02:56
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:02:19
New Information		
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)	05 Oct 2020 19:08:37
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.' canceled (Site from Safety).		29 Sep 2020 21:50:24
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).		25 Sep 2020 17:16:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:57:14
User entered empty.		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	10 Feb 2021 18:57:14
User closed query 'PV Query: Please provide treatment given for the event. 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).		29 Sep 2020 16:43:03
User closed query 'PV Query: Did the subject require oxygen for hypoxia?' (Site from Safety).		29 Sep 2020 16:42:59
Query 'PV Query: Please provide treatment given for the event. 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 'none' (Site from Safety).		28 Sep 2020 20:39:02
Query 'PV Query: Did the subject require oxygen for hypoxia?' answered with 'no' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 20:38:57
User opened query 'PV Query: Please provide treatment given for the event. 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).		25 Sep 2020 17:17:04
User opened query 'PV Query: Did the subject require oxygen for hypoxia?' (Site from Safety).		25 Sep 2020 17:16:51
User entered empty.		18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:14:11

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 23:27:16

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:37:58
Comment added 'CLARIFICATION: Information has been changed back to Hematochezia as per source. Subject's episode of hematochezia was due to a pre existing diagnosis of hemorrhoids with a prior episode reported about 10 years ago in 2010. Please see updated Medhx.'	Frances Saubon (b) (4)	16 Nov 2020 20:38:29
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Haematochezia, LLT: Hematochezia - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:37:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:37:47
Data point term sent to Coder	System	16 Nov 2020 20:37:24
Coding entries removed.	Frances Saubon (b) (4)	16 Nov 2020 20:37:18
User entered 'Hematochezia' reason for change: New Information	Frances Saubon (b) (4)	16 Nov 2020 20:37:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Hemorrhoids - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:26:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:26:47
Data point term sent to Coder	System	16 Nov 2020 20:26:08
Query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable. ' ' answered with 'updated per corrected source' (Site from DM).	Elisa Moralez (b) (4)	16 Nov 2020 20:25:48

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Elisa Moralez (b) (4)	16 Nov 2020 20:25:38
User entered 'hemorrhoids' reason for change: New Information	(b) (4)	
User entered 'hemorrhoids' reason for change: New Information	Elisa Moralez (b) (4)	16 Nov 2020 20:25:38
User entered 'hemorrhoids' reason for change: New Information	(b) (4)	
User opened query 'Per DM CLR: Please review if this symptom was caused by an underlying medical condition. If yes, update AE term to reflect the underlying medical condition as appropriate. Please reconcile with Con Med eCRF as applicable. '(Site from DM).	(b) (4), (b) (6)	06 Nov 2020 09:46:46
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Haematochezia, LLT: Hematochezia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 14:56:36
User coded data point as Term Coded data point by User: Coder System - 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)	21 Oct 2020 14:56:36
Data point term sent to Coder	(b) (4)	
User entered 'Hematochezia'	System	21 Oct 2020 14:55:47
User entered 'Hematochezia'	Frances Saubon (b) (4)	21 Oct 2020 14:55:13
User entered 'Hematochezia'	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered '28 Sep 2020'	Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:55:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:55:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered '0'	Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Not Related (NOT RELATED)'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Not Related (NOT RELATED)'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'I'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered '0'	Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered '0'	Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	21 Oct 2020 14:55:13
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:14:11

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 14:55:13

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User closed query 'Per MM, if this is a prolonged event, please update the term to a medical diagnosis such as hypertension. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Mar 2021 14:53:16
User coded data point as SOC: Vascular disorders, HLTG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 16:45:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 16:45:52
Data point term sent to Coder	System	16 Mar 2021 16:44:26
Query 'Per MM, if this is a prolonged event, please update the term to a medical diagnosis such as hypertension. ' answered with 'updated to hypertension, thank you' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	16 Mar 2021 16:44:14
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	16 Mar 2021 16:44:03
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	16 Mar 2021 16:44:03
User entered 'hypertension' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	16 Mar 2021 16:44:03
User opened query 'Per MM, if this is a prolonged event, please update the term to a medical diagnosis such as hypertension. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 13:30:29
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 01:54:59
User coded data point as SOC: Investigations, HLTG: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure increased, LLT: Increased blood pressure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:59:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:59:32
Data point term sent to Coder	System	21 Oct 2020 14:58:53
User entered 'Elevated Blood Pressure'	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered 'No (N)'	Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered '08 Oct 2020'	Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered 'No (N)'	Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered '0'	Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered '0'	Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered '0'	Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Not Related (NOT RELATED)'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Not Related (NOT RELATED)'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

None

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered 'I'	Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered '0'	Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	21 Oct 2020 14:58:07
	(b) (4)	

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 14:58:07

US3322006

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:14:11

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	21 Oct 2020 14:58:07

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:14:11

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:43:06
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	10 Feb 2021 18:57:20
User closed query 'Per ETRTR: Please add Medication dosed for COVID-19, thanks.' (Site from CRA).		15 Nov 2020 21:00:22
Query 'Per ETRTR: Please add Medication dosed for COVID-19, thanks.' answered with 'all medications in source are entered' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 17:36:11
User opened query 'Per ETRTR: Please add Medication dosed for COVID-19, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 14:26:05
User entered 'Yes (Y)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	24 Aug 2020 16:25:04
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	17 Aug 2020 19:28:51

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 20:06:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	29 Oct 2020 20:06:45
Data point term sent to Coder Coding entries removed.	System	29 Oct 2020 20:05:25
	Elisa Moralez (b) (4)	29 Oct 2020 20:05:07
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Sep 2020 07:37:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Sep 2020 07:37:44
Data point term sent to Coder	System	25 Sep 2020 13:32:28
User closed query 'CDM-Coding: The trade name PROAIR can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	System	25 Sep 2020 13:32:07
Query 'CDM-Coding: The trade name PROAIR can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' answered with 'information clarified by CRC, thank you' (Site from System).	Elisa Moralez (b) (4)	25 Sep 2020 13:32:07

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:11

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'albuterol sulfate' reason for change: New Information	Elisa Moralez (b) (4)	25 Sep 2020 13:31:51
User opened query 'CDM-Coding: The trade name PROAIR can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	Coder Import (b) (4)	23 Sep 2020 10:10:45
Data point term sent to Coder	System	22 Sep 2020 20:20:27
User entered 'Proair'	Frances Saubon (b) (4)	22 Sep 2020 20:20:11
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:20:11
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Asthma'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:20:11
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 puff." Please provide the actual dose for this medication 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)	22 Oct 2020 06:32:54
Query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 puff." Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 21:23:37
User entered '90' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 21:23:25
User opened query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "1 puff." Please provide the actual dose for this medication 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)	21 Oct 2020 05:05:20
User entered '2'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:20:11

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4) Frances Saubon (b) (4)	21 Oct 2020 21:23:25
User entered 'puff (PUFF)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:20:11

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:20:11
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'as needed (PRN)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:20:11
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:20:11
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Per Query Resolution	(b) (4) Elisa Moralez (b) (4)	29 Oct 2020 20:05:07
User entered 'Other (OTHER)'	Frances Saubon (b) (4)	22 Sep 2020 20:20:11
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per CDM: Please review the route of administration for this medication as "Respiratory (Inhalation)" is an option provided within the drop-down menu of Route of administration. For more information follow the CCGs page 37 and update as needed, else provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:52:26
Query 'Per CDM: Please review the route of administration for this medication as "Respiratory (Inhalation)" is an option provided within the drop-down menu of Route of administration. For more information follow the CCGs page 37 and update as needed, else provide clarification. ' answered with 'done' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 20:05:11
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	29 Oct 2020 20:05:07
User opened query 'Per CDM: Please review the route of administration for this medication as "Respiratory (Inhalation)" is an option provided within the drop-down menu of Route of administration. For more information follow the CCGs page 37 and update as needed, else provide clarification. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 19:15:36
Query 'Per CDM: Please review the route of administration for this medication as "Inhalation" is an option provided within the drop-down menu of Route of administration. For more information follow the CCGs page 37 and update as needed, else provide clarification. ' canceled (Site from DM).		28 Oct 2020 19:15:12
User opened query 'Per CDM: Please review the route of administration for this medication as "Inhalation" is an option provided within the drop-down menu of Route of administration. For more information follow the CCGs page 37 and update as needed, else provide clarification. ' (Site from DM).		28 Oct 2020 19:14:53
User entered 'inhalation'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:20:11

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'UN UNK 2012'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:20:11
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:20:11
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:20:11
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	22 Sep 2020 20:20:11
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:20:11
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:20:11

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:20:11

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:14:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:20:11

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE, PRODUCTSYNONYM: BC [ACETYLSALICYLIC ACID;CAFFEINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 16:26:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 16:26:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 01:54:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:04:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:04:38
Data point term sent to Coder Coding entries removed.	System Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:22:49 09 Nov 2020 16:22:32
User entered 'Aspirin (NSAID*) 845mg/Caffeine 65 mg(BC Powder)' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:22:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: BC HEADACHE [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:54:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:54:49
Data point term sent to Coder	System	22 Sep 2020 20:22:30

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Aspirin (BC powder)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:22:22

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:22:22
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 12:16:10
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria' answered with 'Intermittent tension headaches is in MH, please clarify ' (Site from DM).	Frances Saubon (b) (4) (b) (4)	21 Oct 2020 15:04:41
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 07:16:34

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

[Indication](#)

Audit	User	Time (GMT)
User entered 'Intermittent Tension Headaches'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:22:22

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125). ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:44:38
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125). ' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:22:37
User entered '845/65' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:22:32
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125). ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:41:18
User entered '845'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:22:22

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'mg (mg)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:22:22
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	22 Sep 2020 20:22:22
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'as needed (PRN)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:22:22
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	22 Sep 2020 20:22:22
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Oral (ORAL)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:22:22
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	22 Sep 2020 20:22:22
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'UN Jan 2019'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:22:22
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered '0'	Frances Saubon (b) (4)	22 Sep 2020 20:22:22
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:22:22
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	22 Sep 2020 20:22:22
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:22:22
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:22:22

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:22:22

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:14:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:22:22

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:14:11

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE, PRODUCTSYNONYM: BC [ACETYLSALICYLIC ACID;CAFFEINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 16:26:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 16:26:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 01:54:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:05:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:05:39
Data point term sent to Coder Coding entries removed.	System Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:23:50 09 Nov 2020 16:23:01
User entered 'Aspirin (NSAID*) 845mg/Caffeine 65 mg(BC Powder)' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:23:01
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: BC HEADACHE [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:54:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:54:49
Data point term sent to Coder	System	22 Sep 2020 20:23:31

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:14:11

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Aspirin (BC Powder)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:23:24

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:14:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:23:24
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:14:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Migraine Headaches'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:23:24
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:14:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125). ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:44:56
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125). ' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:23:09
User entered '845/65' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:23:01
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125). ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:41:37
User entered '845'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:23:24

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:14:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'mg (mg)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:23:24
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:14:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	22 Sep 2020 20:23:24
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:14:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'as needed (PRN)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:23:24
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:14:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	22 Sep 2020 20:23:24
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:14:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Oral (ORAL)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:23:24
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:14:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	22 Sep 2020 20:23:24
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:14:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'UN UNK 2019'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:23:24
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:14:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:23:24
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:14:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:23:24
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:14:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	22 Sep 2020 20:23:24
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:14:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:23:24
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:14:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:23:24

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:14:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:23:24

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:14:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 20:23:24

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE, PRODUCTSYNONYM: BC [ACETYLSALICYLIC ACID;CAFFEINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 16:26:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 16:26:51
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 01:54:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:19:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:19:40
Data point term sent to Coder Coding entries removed.	System Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:25:51 09 Nov 2020 16:24:57
User entered 'Aspirin (NSAID*) 845 mg/Caffeine 65 mg(BC Powder)' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:24:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: BC HEADACHE [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:55:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 05:55:40

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	22 Sep 2020 20:24:34
User entered 'Aspirin (BC Powder)'	Frances Saubon (b) (4)	22 Sep 2020 20:24:29
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the eDiary CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 01:00:53
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the eDiary CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' answered with 'Corrected. Medication was not taken prophylactically. ' (Site from DM).	Blessing Felix-Okoroji (b) (4)	06 Nov 2020 15:03:06
User entered 'No (N)' reason for change: Per Query Resolution	Blessing Felix-Okoroji (b) (4)	06 Nov 2020 15:02:45
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the eDiary CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:42:25
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:20:29
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'Per protocol ARs that start and stop during the 7 days post dose e-diary are recorded by the e-diary and do not need to be entered in CRF as a separate entry.' (Site from DM).	Blessing Felix-Okoroji (b) (4)	06 Nov 2020 15:04:38

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM). User entered 'Headache'	(b) (4), (b) (6)	06 Nov 2020 10:42:08
	Frances Saubon (b) (4)	22 Sep 2020 20:24:29
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:45:10
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' answered with 'updated' (Site from DM).	Frances Saubon (b) (4)	09 Nov 2020 16:25:03
User entered '845/65' reason for change: Per Query Resolution	Frances Saubon (b) (4)	09 Nov 2020 16:24:57
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:42:34
User entered '845'	Frances Saubon (b) (4)	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'mg (mg)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'once daily (QD)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Oral (ORAL)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '22 Aug 2020'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '23 Aug 2020'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Frances Saubon (b) (4)	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:20
User entered '1'	System	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:20
User entered '1'	System	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:14:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:20
User entered '804 (804)'	System	22 Sep 2020 20:24:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:14:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 07:57:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 07:57:08
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 16:00:34
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' answered with 'Per source, Seasonal allergies were not worsening' (Site from DM).	Frances Saubon (b) (4)	16 Nov 2020 20:36:38
Data point term sent to Coder	System	11 Nov 2020 23:01:33
Coding entries removed.	Blessing Felix-Okoroji (b) (4)	11 Nov 2020 23:00:54
User entered 'Loratadine (CLARITIN)' reason for change: New Information	Blessing Felix-Okoroji (b) (4)	11 Nov 2020 23:00:54

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:14:11

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 16:26:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 16:26:35
Data point term sent to Coder Coding entries removed.	System Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:25:53 09 Nov 2020 16:25:32
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:43:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 14:39:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 14:39:33
Data point term sent to Coder User entered 'Claritin'	System Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:39:00 22 Oct 2020 14:38:32

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:14:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:38:32
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:14:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matche.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:48:10
Query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matche.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:25:40
User entered 'Seasonal Allergies' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:25:32
User opened query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matche.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:43:31
User entered 'Allergies'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:38:32

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:14:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '10' reason for change: New Information	(b) (4) Blessing Felix-Okoroji (b) (4)	11 Nov 2020 23:00:54
User entered '1'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:38:32

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:14:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4) Blessing Felix-Okoroji (b) (4)	11 Nov 2020 23:00:54
User entered 'tablet (TABLET)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:38:32

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:14:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:38:32
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:14:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'as needed (PRN)'	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:38:32
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:14:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:38:32
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:14:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Oral (ORAL)'	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:38:32
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:14:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:38:32
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:14:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '28 Sep 2020'	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:38:32
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:14:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Elisa Moralez (b) (4)	22 Oct 2020 14:38:32
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:14:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:38:32
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:14:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:38:32
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:14:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	22 Oct 2020 14:38:32
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:14:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:38:32

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:14:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:38:32

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:14:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:38:32

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Jan 2021 19:54:04
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' answered with 'per source, seasonal allergies were not worsening.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	13 Jan 2021 17:26:04
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening SEASONAL ALLERGIES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 16:47:47
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: OTHER OPHTHALMOLOGICALS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:25:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:25:54
Data point term sent to Coder	System	24 Nov 2020 16:05:39
User closed query 'CDM-Coding, if unknown the ingredients please add 'Unknown' to the term in bracket.' (Site from System).	System	24 Nov 2020 16:04:57
Query 'CDM-Coding, if unknown the ingredients please add 'Unknown' to the term in bracket.' answered with 'term changed per query resolution' (Site from System).	Frances Saubon (b) (4) (b) (4)	24 Nov 2020 16:04:57

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'ANTI HISTAMINE EYE DROPS [unknown]' reason for change: Data Entry Error	Frances Saubon (b) (4)	24 Nov 2020 16:04:42
User opened query 'CDM-Coding, if unknown the ingredients please add 'Unknown' to the term in bracket.' (Site from System).	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	24 Nov 2020 01:55:01
Data point term sent to Coder	(b) (4)	
User closed query 'Per DM CLR: Please note that ConMed details cannot be verified. Please review and update Name of Medication to provide the generic components of this medication. Please review and update eCRF as appropriate.' (Site from DM).	System	12 Nov 2020 14:51:05
Query 'Per DM CLR: Please note that ConMed details cannot be verified. Please review and update Name of Medication to provide the generic components of this medication. Please review and update eCRF as appropriate.' answered with 'Please see last reply. The subject does not remember the name of the eye drops that they took. Thank you' (Site from DM).	System	09 Nov 2020 16:30:59
User opened query 'Per DM CLR: Please note that ConMed details cannot be verified. Please review and update Name of Medication to provide the generic components of this medication. Please review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 01:12:02
User opened query 'Per DM CLR: Please note that ConMed details cannot be verified. Please review and update Name of Medication to provide the generic components of this medication. Please review and update eCRF as appropriate.' (Site from DM).	Blessing Felix-Okoroji (b) (4)	06 Nov 2020 14:37:35
User opened query 'Per DM CLR: Please note that ConMed details cannot be verified. Please review and update Name of Medication to provide the generic components of this medication. Please review and update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:38:45
Data point term sent to Coder	System	23 Oct 2020 15:20:30
User closed query 'DM-Coding: This medication cannot be referenced as reported. Please enter a trade name with the generic/active ingredient(s) in the drug name field. Please make your changes to the reported term.' (Site from System).	System	23 Oct 2020 15:19:52

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'DM-Coding: This medication cannot be referenced as reported. Please enter a trade name with the generic/active ingredient(s) in the drug name field. Please make your changes to the reported term.' answered with 'Patient does not remember medication name or active ingredients. Other common medications of this type have the ingredients "Naphazoline HCl and Pheniramine Maleate" but we are not sure that this is what the patient used. Should we update with this information or take other action? Please advise, thank you.' (Site from System).	Elisa Moralez (b) (4)	23 Oct 2020 15:19:52
User opened query 'DM-Coding: This medication cannot be referenced as reported. Please enter a trade name with the generic/active ingredient(s) in the drug name field. Please make your changes to the reported term.' (Site from System).	Coder Import (b) (4)	23 Oct 2020 08:36:26
Data point term sent to Coder	System	22 Oct 2020 14:40:01
User entered 'Antihistamine Eye Drops'	Elisa Moralez (b) (4)	22 Oct 2020 14:39:06

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:39:06
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matche.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 17:50:20
Query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matche.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:30:47
User entered 'SEASONAL ALLERGIES' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 16:30:41
User opened query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matche.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:40:27
User entered 'Allergies'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:39:06

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '2'	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:39:06
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Other (OTHER)'	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:39:06
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'drops'	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:39:06
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'as needed (PRN)'	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:39:06
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:39:06
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:53:57
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated per changed source' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	12 Nov 2020 14:51:09
User entered 'Topical (TOPICAL)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	12 Nov 2020 14:50:52
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:40:37
User entered 'Intraocular (INTRAOCULAR)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:39:06

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:39:06
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '28 Sep 2020'	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:39:06
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '0'	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:39:06
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'Yes (Y)'	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:39:06
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	(b) (4) Elisa Morales (b) (4)	22 Oct 2020 14:39:06
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	22 Oct 2020 14:39:06
	(b) (4)	

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:39:06

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:39:06

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:14:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 14:39:06

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:14:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:18:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:59:33
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: NYQUIL SEVERE COLD & FLU - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:12:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 20:12:24
Data point term sent to Coder	System	22 Oct 2020 14:42:06
User entered 'Nyquil [Acetaminophen, Dextromethorphan hydrobromide, Doxylamine succinate Phenylephrine hydrochloride]'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:14:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:18:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:59:33
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:14:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:18:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:59:33
User entered 'symptomatic COVID-19'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:14:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:18:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:59:33
User entered '650/20/12.5/10'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:14:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:18:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:59:33
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:14:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:18:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:59:33
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:14:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:18:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:59:33
User entered 'as needed (PRN)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:14:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:18:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:59:33
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:14:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:18:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:59:33
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:14:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:18:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:59:33
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:14:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:18:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:59:33
User entered '09 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:14:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:18:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:59:33
User entered '0'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:14:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:18:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:59:33
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:14:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:18:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:59:33
User entered '18 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:14:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:18:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 18:59:33
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:14:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:18:26
User entered empty.	System	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:14:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:18:26
User entered empty.	System	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:14:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:18:26
User entered empty.	System	22 Oct 2020 14:42:04

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:14:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:24
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE, PRODUCTSYNONYM: ASPIRIN/CAFFEINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Mar 2021 16:32:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Mar 2021 16:32:53
Data point term sent to Coder	System	22 Mar 2021 16:31:26
User entered 'Aspirin/Caffeine'	Elisa Moralez (b) (4)	22 Mar 2021 16:30:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:14:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:24
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	22 Mar 2021 16:30:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:14:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:24
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM).		31 Mar 2021 15:05:20
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' answered with 'part of part B so will be removed' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	30 Mar 2021 19:48:47
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 08:17:56
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 21:49:41
User entered 'Headache'	Elisa Moralez (b) (4) (b) (4)	22 Mar 2021 16:30:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:14:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:24
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered '845/65'	(b) (4) Elisa Moralez (b) (4)	22 Mar 2021 16:30:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:14:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:24
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered 'mg (mg)'	(b) (4) Elisa Moralez (b) (4)	22 Mar 2021 16:30:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:14:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:24
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered empty.	(b) (4) Elisa Moralez (b) (4)	22 Mar 2021 16:30:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:14:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:24
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered 'once (ONCE)'	(b) (4) Elisa Moralez (b) (4)	22 Mar 2021 16:30:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:14:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:24
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered empty.	(b) (4) Elisa Moralez (b) (4)	22 Mar 2021 16:30:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:14:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:24
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered 'Oral (ORAL)'	(b) (4) Elisa Moralez (b) (4)	22 Mar 2021 16:30:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:14:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:24
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered empty.	(b) (4) Elisa Moralez (b) (4)	22 Mar 2021 16:30:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:14:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:24
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered '06 Feb 2021'	(b) (4) Elisa Moralez (b) (4)	22 Mar 2021 16:30:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:14:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:24
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered '0'	(b) (4) Elisa Moralez (b) (4)	22 Mar 2021 16:30:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:14:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:24
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	22 Mar 2021 16:30:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:14:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:24
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered '06 Feb 2021'	(b) (4) Elisa Moralez (b) (4)	22 Mar 2021 16:30:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:14:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:24
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 21:49:41
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4)	22 Mar 2021 16:30:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:14:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:24
User entered empty.	System	22 Mar 2021 16:30:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:14:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:24
User entered empty.	System	22 Mar 2021 16:30:29

US3322006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:14:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:33:24
User entered empty.	System	22 Mar 2021 16:30:29

US3322006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:14:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4)	17 Aug 2020 19:29:17
	(b) (4)	

US3322006

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:14:11

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered '9 Sep 2020'	Elisa Moralez (b) (4)	23 Sep 2020 20:46:31

US3322006

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:14:11

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User closed query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 09:28:05
Query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' answered with 'subject is still participating in the study for follow up. ' (Site from DM).	Frances Saubon (b) (4) (b) (4)	30 Sep 2020 14:34:34
User opened query 'Per CDM: Primary reason for dosing discontinuation is recorded as 'Due to SARS-COV-2',However, no data is recorded on 'End of Study / Study Discontinuation' form. Kindly verify and consider to update all the necessary eCRFs required else clarify.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 09:27:48
User entered 'Due to SARS-COV-2 (COVID)'	Elisa Moralez (b) (4) (b) (4)	23 Sep 2020 20:46:31

US3322006

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:14:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:10:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
User entered empty.	Elisa Moralez (b) (4)	23 Sep 2020 20:46:31

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (v) (+), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'USA-US060-2020-MRNA-1273-P301000003'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (v) (+), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'Veronica'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'Fragoso'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered '6550 Mapleridge Street'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'Houston'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'TX'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered '77081'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		29 Sep 2020 16:43:15
User entered 'US'	System	20 Sep 2020 18:20:06

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered '3'	System	07 Oct 2020 13:25:11
User entered '2'	System	29 Sep 2020 16:43:23
User entered '1'	System	20 Sep 2020 18:20:06

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'USA-US060-2020-MRNA-1273-P301000003'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'Veronica'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'Fragoso'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered '6550 Mapleridge Street'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'Houston'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'TX'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered '77081'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		29 Sep 2020 16:43:15
User entered 'US'	System	20 Sep 2020 18:20:06

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered '3'	System	07 Oct 2020 13:25:11
User entered '2'	System	29 Sep 2020 16:43:23
User entered '1'	System	20 Sep 2020 18:20:06

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:14:11

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
User entered '20/Sep/2020 14:20'	System	20 Sep 2020 18:20:06

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:14:11

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.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		29 Sep 2020 16:43:15
User entered '1'		20 Sep 2020 18:20:06

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'USA-US060-2020-MRNA-1273-P301000003'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (u) (+), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'Veronica'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'Fragoso'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered '6550 Mapleridge Street'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'Houston'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'TX'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered '77081'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		29 Sep 2020 16:43:15
User entered 'US'	System	20 Sep 2020 18:20:06

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered '3'	System	07 Oct 2020 13:25:11
User entered '2'	System	29 Sep 2020 16:43:23
User entered '1'	System	20 Sep 2020 18:20:06

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:14:11

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
User entered '29/Sep/2020 12:43'	System	29 Sep 2020 16:43:23

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:14:11

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.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		07 Oct 2020 13:25:00
User entered '1'		29 Sep 2020 16:43:23

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'USA-US060-2020-MRNA-1273-P301000003'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'Veronica'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'Fragoso'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered '6550 Mapleridge Street'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'Houston'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'TX'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered '77081'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		29 Sep 2020 16:43:15
User entered 'US'	System	20 Sep 2020 18:20:06

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered '3'	System	07 Oct 2020 13:25:11
User entered '2'	System	29 Sep 2020 16:43:23
User entered '1'	System	20 Sep 2020 18:20:06

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:14:11

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
User entered '07/Oct/2020 13:25'	System	07 Oct 2020 13:25:11

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:14:11

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.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		07 Oct 2020 15:23:39
User entered '1'		07 Oct 2020 13:25:11

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'USA-US060-2020-MRNA-1273-P301000003'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Death

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'No (N)'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'Veronica'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'Fragoso'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered '6550 Mapleridge Street'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'Houston'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered 'TX'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		20 Sep 2020 18:19:59
User entered '77081'	System	20 Sep 2020 18:19:37

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 20:16:14
Reviewed for Safety.		29 Sep 2020 16:43:15
User entered 'US'	System	20 Sep 2020 18:20:06

US3322006

Folder: SAE USA-US060-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 11 Aug 2021 22:14:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 01:54:59
	(b) (4)	
User entered '3'	System	07 Oct 2020 13:25:11
User entered '2'	System	29 Sep 2020 16:43:23
User entered '1'	System	20 Sep 2020 18:20:06