

US3702010 (Prod: Weill Cornell Chelsea - (CRS))

Generated By: KC Joubran

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US3702010

Form: Participant Creation

Data signed: (b) (4) 15 Mar 2021 20:14:58

Generated On: 10 Jun 2021 09:17:27

Participant ID

US3702010

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

US3702010

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 20:15:16

Generated On: 10 Jun 2021 09:17:27

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 04 SEP 2020

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

Folder OID SCRN

US3702010

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Date of Birth (MMM yyyy)	(b) (6) 1946
Age	74
Age Units	YEARS
Age (Derived)	74
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	_____
Unknown	True
Not reported	False

US3702010

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Date of Informed Consent (*dd MMM yyyy*) 4 SEP 2020

Month and Year of Informed Consent (derived) SEP 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

US3702010

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Did the participant meet all eligibility criteria?

Yes

No

US3702010

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Condition	CIRRHOSIS OF LIVER DUE TO HEPATITIS C
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

US3702010

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Condition	HUMAN IMMUNODEFICIENCY VIRUS INFECTION
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3702010

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

US3702010

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Condition	ESOPHAGEAL VARICES WITH H/O BANDING
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3702010

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Condition	PORTAL HYPERTENSIVE GASTROPATHY
Start date (dd MMM yyyy)	10 OCT 2019
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)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Condition	LIPODYSTROPHY DUE TO AIDS ANTIRETROVIRAL THERAPY
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Condition	INSULIN RESISTANCE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Condition	COLONIC POLYPS
Start date (dd MMM yyyy)	UN UNK 2013
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)	
Stop date completely unknown	True
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

US3702010

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Condition	BENIGN PROSTATIC HYPERPLASIA ASSOCIATED WITH NOCTURIA
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)	

US3702010

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Condition	EXERCISE-INDUCED RIGHT BUNDLE BRANCH BLOCK DURING EXERCISE STRESS TEST - ASYMPTOMATIC
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)	

US3702010

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Condition	CONSTIPATION
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3702010

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Mar 2021 20:15:16

Generated On: 10 Jun 2021 09:17:27

Were vital signs assessed? Yes
No

Date of assessment (*dd MMM yyyy*) 04 SEP 2020

Time of assessment (*00:00-23:59*) 13:43 (24 HR)

Vital Signs Date and Time (derived) 04 SEP 2020 13:43

Height (*xxx.x*) 164 cm

Weight (*xxx.x*) 92.7 kg

BMI (*xxx.x*) 34.46609 kg/m²

BMI units KG/M2

Temperature (*xxx.x*) ND - Not Done

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (*xxx*) ND - Not Done

Pulse units BPM

Respiratory Rate (*xxx*) ND - Not Done

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (*xxx*) ND - Not Done

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (*xxx*) ND - Not Done

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3702010

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

04 SEP 2020

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

US3702010

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Mar 2021 20:15:16

Generated On: 10 Jun 2021 09:17:27

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes No

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Mar 2021 20:15:16

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

US3702010

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 20:14:23

Generated On: 10 Jun 2021 09:17:27

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 04 SEP 2020

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

Folder OID VISIT1

US3702010

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Mar 2021 20:14:23

Generated On: 10 Jun 2021 09:17:27

What was the date of randomization? (dd MMM yyyy) 04 SEP 2020

What was the participant's randomization number? 188150

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) 15 Mar 2021 20:14:23

Generated On: 10 Jun 2021 09:17:27

Height	ND - Not Done
Weight	ND - Not Done

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Mar 2021 20:14:23

Generated On: 10 Jun 2021 09:17:27

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	13:43 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 13:43
Temperature (<i>xxx.x</i>)	37.2 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	76 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Mar 2021 20:14:23

Generated On: 10 Jun 2021 09:17:27

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	15:52 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 15:52
Temperature (<i>xxx.x</i>)	36.1 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	61 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3702010

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 20:14:23

Generated On: 10 Jun 2021 09:17:27

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.

US3702010

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Mar 2021 20:15:16

Generated On: 10 Jun 2021 09:17:27

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) 4 SEP 2020

What was the treatment time? (00:00-23:59) 14:21 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 14:21

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

US3702010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Mar 2021 20:15:16

Generated On: 10 Jun 2021 09:17:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	04 SEP 2020
Collection time (<i>00:00-23:59</i>)	13:56 (24 HR)
Collection date and time (derived)	04 SEP 2020 13:56

US3702010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Mar 2021 20:15:16

Generated On: 10 Jun 2021 09:17:27

Collection date (<i>dd MMM yyyy</i>)	04 SEP 2020		
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:20	04 SEP 2020 14:20
Nasopharyngeal Swab 2	No		

US3702010

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 20:15:16

Generated On: 10 Jun 2021 09:17:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.0 °F

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

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

PC Time Stamp 04 SEP 2020 15:02

PC Open Date & Time 04 SEP 2020 14:41

PC Close Date & Time 04 SEP 2020 17:11

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

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** 97.2 °F

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

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

PC Time Stamp 04 SEP 2020 21:42
PC Open Date & Time 04 SEP 2020 18:06
PC Close Date & Time 05 SEP 2020 11:59

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:27

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	98.3 °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	05 SEP 2020 20:18
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:27

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

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

PC Time Stamp	06 SEP 2020 21:57
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:27

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

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

PC Time Stamp	07 SEP 2020 21:59
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:27

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	97.3 °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	09 SEP 2020 01:05
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes
No

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

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred _____
To **PREVENT** pain or fever from occurring _____
PC Time Stamp _____
PC Open Date & Time 09 SEP 2020 12:00
PC Close Date & Time 10 SEP 2020 11:59

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes
No

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

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred
To **PREVENT** pain or fever from occurring
PC Time Stamp
PC Open Date & Time 10 SEP 2020 12:00
PC Close Date & Time 11 SEP 2020 11:59

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

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

04 SEP 2020 15:03

PC Open Date & Time

04 SEP 2020 14:41

PC Close Date & Time

04 SEP 2020 17:11

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

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

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

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

PC Time Stamp

PC Open Date & Time

04 SEP 2020 18:06

PC Close Date & Time

05 SEP 2020 11:59

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:27

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	05 SEP 2020 20:20
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:27

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

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

33

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

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

06 SEP 2020 22:03

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:27

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	07 SEP 2020 22:00
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:27

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	09 SEP 2020 01:05
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

DAY 6

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

Please select one response below

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

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

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

PC Time Stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

DAY 7

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

Please select one response below

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

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

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

PC Time Stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

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

No

Yes

PC Time stamp	04 SEP 2020 15:03
PC Open Date & Time	04 SEP 2020 14:41
PC Close Date & Time	04 SEP 2020 17:11

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

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

No

Yes

PC Time stamp

PC Open Date & Time

04 SEP 2020 18:06

PC Close Date & Time

05 SEP 2020 11:59

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:27

	Yes <input type="checkbox"/>
PC Time stamp	05 SEP 2020 20:22
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:27

	Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 22:04
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:27

	Yes <input type="checkbox"/>
PC Time stamp	07 SEP 2020 22:03
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:27

Yes

PC Time stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:27

Yes

PC Time stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:27

Yes

PC Time stamp

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3702010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 11 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3702010

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3702010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 21 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3702010

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3702010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 28 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3702010

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3702010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 20:14:23

Generated On: 10 Jun 2021 09:17:27

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 02 OCT 2020

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

Folder OID VISIT2

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Mar 2021 20:14:23

Generated On: 10 Jun 2021 09:17:27

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>)	02 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	18:18 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 18:18
Temperature (<i>xxx.x</i>)	37.2 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Mar 2021 20:14:23

Generated On: 10 Jun 2021 09:17:27

Timepoint Pre-Dose
Post-Dose

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 _____

US3702010

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 20:14:23

Generated On: 10 Jun 2021 09:17:27

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

02 OCT 2020

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

US3702010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Mar 2021 20:14:23

Generated On: 10 Jun 2021 09:17:27

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

PARTICIPANT REFUSED SECOND INJECTION DUE TO SIDE EFFECTS HE EXPERIENCED. HE CONSENTED TO CONTINUE WITH STUDY VISITS.

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? _____

US3702010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 15:29:06

Generated On: 10 Jun 2021 09:17:27

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 02 OCT 2020

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

Collection date and time (derived) 02 OCT 2020 15:24

US3702010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 29 Apr 2021 15:29:06

Generated On: 10 Jun 2021 09:17:27

Collection date (<i>dd MMM yyyy</i>)			02 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:35	02 OCT 2020 15:35
Nasopharyngeal Swab 2	No		

US3702010

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 20:14:23

Generated On: 10 Jun 2021 09:17:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3702010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 9 OCT 2020

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

Comments PATIENT WAS UNABLE TO REACH

If Contact Not Made, please provide Comments

US3702010

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3702010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3702010

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3702010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3702010

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3702010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 20:14:23

Generated On: 10 Jun 2021 09:17:27

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 30 OCT 2020

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

Folder OID VISIT3

US3702010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Mar 2021 20:14:23

Generated On: 10 Jun 2021 09:17:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFORMATION NOT SPECIFIED.
Pulse (<i>xxx</i>)	62 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3702010

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 20:14:23

Generated On: 10 Jun 2021 09:17:27

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

30 OCT 2020

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

US3702010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Mar 2021 20:14:23

Generated On: 10 Jun 2021 09:17:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	30 OCT 2020
Collection time (<i>00:00-23:59</i>)	15:54 (24 HR)
Collection date and time (derived)	30 OCT 2020 15:54

US3702010

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 20:14:23

Generated On: 10 Jun 2021 09:17:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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)	_____
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 <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"/>

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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"/>

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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"/>

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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 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"/>

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT DAY 138

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

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

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

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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 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"/>

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3702010

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:17:27

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
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US3702010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 25 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3702010

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3702010

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3702010

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3702010

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

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 _____

US3702010

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3702010

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 13:11:29

Generated On: 10 Jun 2021 09:17:27

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 _____

US3702010

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 20:15:15

Generated On: 10 Jun 2021 09:17:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3702010

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

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 _____

US3702010

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

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)	_____

US3702010

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:27

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.

US3702010

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:27

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) _____

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

Collection date and time (derived) _____

US3702010

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 15 Mar 2021 20:15:12

Generated On: 10 Jun 2021 09:17:27

Date of Contact 05 JAN 2021

Time of Contact

Date and Time of Contact (derived)

Type of Contact

Clinic Visit - Scheduled

Clinical Visit - Unscheduled

Safety Call

Convalescent Tele-visit

Has the subject reported symptoms of SARS-COV-2?

Yes

No

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

Date 05 JAN 2021

Assessment Not Done True

O2 Saturation 90 %

O2 Saturation Units %

Temperature 38.3 C

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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"/>

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

	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 JAN 2021

Assessment Not Done False

O2 Saturation 94 %

O2 Saturation Units %

Temperature 36.9 C

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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"/>

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

Date	06 JAN 2021
------	-------------

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

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

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

Temperature	36.8 C
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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"/>

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

Date 07 JAN 2021

Assessment Not Done False

O2 Saturation 96 %

O2 Saturation Units %

Temperature 36.8 C

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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"/>

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

Date 08 JAN 2021

Assessment Not Done False

O2 Saturation 94 %

O2 Saturation Units %

Temperature ND - Not Done

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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"/>

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

Date 09 JAN 2021

Assessment Not Done False

O2 Saturation 94 %

O2 Saturation Units %

Temperature 37.1 C

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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"/>

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

	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 JAN 2021

Assessment Not Done False

O2 Saturation 94 %

O2 Saturation Units %

Temperature 37.3 C

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

	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 JAN 2021

Assessment Not Done False

O2 Saturation 93 %

O2 Saturation Units %

Temperature 36.8 C

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

	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 JAN 2021

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

Difficulty Breathing

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

	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 JAN 2021

Assessment Not Done False

O2 Saturation 94 %

O2 Saturation Units %

Temperature 97.7 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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

	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 JAN 2021

Assessment Not Done False

O2 Saturation 94 %

O2 Saturation Units %

Temperature 98.1 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

	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 JAN 2021

Assessment Not Done False

O2 Saturation 96 %

O2 Saturation Units %

Temperature 97.5 F

Chills

None

Mild

Moderate

Severe

Not Done

Cough

None

Mild

Moderate

Severe

Not Done

Shortness of Breath

None

Mild

Moderate

Severe

Not Done

Difficulty Breathing

None

Mild

Moderate

Severe

PRODUCTION RELEASE (v12.003

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Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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"/>

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

	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 JAN 2021

Assessment Not Done False

O2 Saturation 93 %

O2 Saturation Units %

Temperature 98.1 F

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

	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 JAN 2021

Assessment Not Done False

O2 Saturation 97 %

O2 Saturation Units %

Temperature 100.8 F

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

	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 JAN 2021
------	-------------

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

O2 Saturation	94 %
---------------	------

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

Temperature	100.1 F
-------------	---------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

Date 01 JAN 2021

Assessment Not Done False

O2 Saturation ND - Not Done

O2 Saturation Units %

Temperature ND - Not Done

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

202 of 2785

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

	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 02 JAN 2021

Assessment Not Done False

O2 Saturation ND - Not Done

O2 Saturation Units %

Temperature ND - Not Done

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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"/>

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

Date 03 JAN 2021

Assessment Not Done False

O2 Saturation ND - Not Done

O2 Saturation Units %

Temperature ND - Not Done

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

Date 04 JAN 2021

Assessment Not Done False

O2 Saturation ND - Not Done

O2 Saturation Units %

Temperature ND - Not Done

Chills

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

Cough

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

Shortness of Breath

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

Difficulty Breathing

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Apr 2021 13:11:29

Generated On: 10 Jun 2021 09:17:27

Date of Visit 08 JAN 2021

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 08 JAN 2021

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

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

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 _____ 05 JAN 2021

End Date _____

Oxygen Saturation _____ 90 %

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 _____ 24 JAN 2021

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes
No

Start Date _____ 20 JAN 2021

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes No

Start Date 20 JAN 2021

End Date 24 JAN 2021

Non-Invasive Ventilation? Yes No

Start Date 21 JAN 2021

End Date 24 JAN 2021

Mechanical Ventilation? Yes No

Start Date 24 JAN 2021

End Date 25 FEB 2021

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 _____

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

Hepatic Dysfunction? Yes
No

Start Date

Neurologic Dysfunction? Yes
No

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes
No

Date of Assessment 05 JAN 2021

Radiographical Evidence Yes
No

Date of Assessment 05 JAN 2021

Admission to an intensive care unit due to SARS-CoV-2 Yes
No

Start Date 24 JAN 2021

End Date 25 FEB 2021

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 15 Mar 2021 20:15:13

Generated On: 10 Jun 2021 09:17:27

[Generate Next COVID-19 Assessment](#)

Yes

No

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 29 Apr 2021 15:29:05

Generated On: 10 Jun 2021 09:17:27

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	11 JAN 2021
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	No	

US3702010

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 20:15:14

Generated On: 10 Jun 2021 09:17:27

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 05 JAN 2021

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

Folder OID SICKD1

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 13:11:29

Generated On: 10 Jun 2021 09:17:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	05 JAN 2021
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	38.3 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFORMATION NOT SPECIFIED
Pulse (<i>xxx</i>)	82 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	170 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3702010

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Mar 2021 20:15:14

Generated On: 10 Jun 2021 09:17:27

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

05 JAN 2021

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

US3702010

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 15 Mar 2021 20:15:14

Generated On: 10 Jun 2021 09:17:27

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

Yes

No

NA (COVID-19 Negative)

Date of Collection

08 JAN 2021

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 13:11:28

Generated On: 10 Jun 2021 09:17:27

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID SICKD28

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 13:11:28

Generated On: 10 Jun 2021 09:17:27

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) _____

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 13:11:28

Generated On: 10 Jun 2021 09:17:27

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.

US3702010

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 16 Apr 2021 13:11:28

Generated On: 10 Jun 2021 09:17:27

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

Yes

No

NA (COVID-19 Negative)

Date of Collection _____

US3702010

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

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

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 _____

US3702010

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

Form: Unblinding

Generated On: 10 Jun 2021 09:17:27

Date of updated informed consent (*dd MMM yyyy*) _____

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

Was the participant unblinded? Yes
No

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

Date of unblinding (*dd MMM yyyy*) _____

Participant randomization assignment mRNA-1273
Placebo

Actual Dose 1 mRNA-1273
Placebo
Not Administered

Actual Dose 2 mRNA-1273
Placebo
Not Administered

Will participant receive mRNA-1273? Yes
No

Placebo Only Flag _____

Continuing with mRNA-1273 _____

US3702010

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:27

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) _____

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

Collection date and time (derived) _____

US3702010

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:17:27

Was the sample collected? Yes

No

Collection date (*dd MMM yyyy*) _____

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

Collection Date and Time (derived) _____

US3702010

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 20:15:04

Generated On: 10 Jun 2021 09:17:27

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Apr 2021 13:11:28

Generated On: 10 Jun 2021 09:17:27

AEID	
Adverse event	NAUSEA
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)	04 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 SEP 2020
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 (5)

Data signed: (b) (4) 16 Apr 2021 13:11:28

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 16 Apr 2021 13:11:28

Generated On: 10 Jun 2021 09:17:27

AEID

Adverse event FATIGUE

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) 05 SEP 2020

Start time (00:00-23:59) 20:22 (24 HR)

AE start date and time (derived) 05 SEP 2020 20:22

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 11 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

Number of Days in ICU

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 16 Apr 2021 13:11:28

Generated On: 10 Jun 2021 09:17:27

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

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 16 Apr 2021 13:11:28

Generated On: 10 Jun 2021 09:17:27

AEID	
Adverse event	FATIGUE
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)	11 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	02 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 16 Apr 2021 13:11:28

Generated On: 10 Jun 2021 09:17:27

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply) None

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

Serious Adverse Event Derived (CSA Programming Field Only) 0

Medically Attended AE Derived (CSA Programming Field Only) 0

Admitted to ICU Derived (CSA Programming Field Only) _____

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 16 Apr 2021 13:11:28

Generated On: 10 Jun 2021 09:17:27

AEID

Adverse event LOWER ABDOMINAL PAIN

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) 23 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 26 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 16 Apr 2021 13:11:28

Generated On: 10 Jun 2021 09:17:27

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

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 16 Apr 2021 13:11:28

Generated On: 10 Jun 2021 09:17:27

AEID USA-US133-2021-MRNA-1273-P30
1000001

Adverse event COVID-19 INFECTION (ONSET
1/1/2021, DIAGNOSIS 1/5/2021)

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) 01 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 25 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

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

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death True

Life threatening True

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 05 JAN 2021

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes
No
Unknown

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Folder: Adverse Events

Form: Adverse Events (13)

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Number of Days in ICU _____

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure True

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with
Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 16 Apr 2021 13:11:28

Generated On: 10 Jun 2021 09:17:27

PT WAS HOSPITALIZED
1/5-1/11/21 FOR COVID-19 (DX
1/5/21). HE WAS HYPOXIC WITH
AMBULATION (O2 SAT 89%)
BUT OTHERWISE MEDICALLY
STABLE WITH NO END ORGAN
DAMAGE. HE DID NOT
REQUIRE ICU OR MECHANICAL
VENTILATION. HE RECEIVED IV
REMDESIVIR AND
DEXAMETHASONE FOR
TREATMENT. PARTICIPANT
WAS SEEN ON 1/5/21 FOR
SYMPTOMS SUGGESTIVE OF
COVID INCLUDING FEVER,
COUGH, AND DYSPNEA ON
EXERTION. HE REPORTED 1/1
AS THE FIRST SX ONSET. AT
VISIT, PT WAS NOTED TO BE
COUGHING AND SHORT OF
BREATH WITH EXERTION AND
EMS WAS CALLED. COVID
PNEUMONIA WAS DIAGNOSED
(PULMONARY INFILTRATES,
HYPOXEMIA, AND PCR
POSITIVE FOR SARS-COV2. HE
WAS RE-HOSPITALIZED
1/11-1/15/21 AND TREATED
WITH REMDESIVIR (5-DAY
COURSE) AND
DEXAMETHASONE. ONCE HOME
HE WAS STABLE UNTIL HE
DISCONTINUED
DEXAMETHASONE ON 1/16. HE
THEN NOTED FEVERS AND

US3702010

Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 16 Apr 2021 13:11:28

Generated On: 10 Jun 2021 09:17:27

WORSENING HYPOXIA AND SHORTNESS OF BREATH AND CALLED EMS ON 1/20/21. PT ADMITTED ON 1/20/21 FOR ACUTE RESPIRATORY FAILURE SECONDARY TO PNEUMONIA REQUIRING HI-FLOW OXYGEN AND BI-LEVEL NON-INVASIVE POSITIVE PRESSURE VENTILATION. DESPITE REINSTITUTION OF STEROIDS, EMPIRIC TREATMENT FOR BACTERIAL PNEUMONIA AND EMPIRIC COVERAGE FOR PNEUMOCYSTIS JIROVECI PNEUMONIA, PT DEVELOPED WORSENING HYPOXEMIA AND WAS INTUBATED ON 1/24 AND TRANSFERRED TO MICU. DURING HIS STAY HE WAS SEDATED AND PARALYZED ON MECHANICAL VENTILATION WITH HIGH VENT REQUIREMENTS, WITH PERSISTENT HYPOXEMIA. HE HAD RECURRENT SVT TREATED WITH AMIODARONE AND CARDIOVERSION, AS WELL AS ELECTROLYTE DISTURBANCES. WORK UP REVEALED NO OTHER MICROBIAL EXPLANATION FOR PNEUMONIA/ARDS OTHER THAN SARS-COV2 (PT REMAINED PCR POSITIVE ON

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 16 Apr 2021 13:11:28

Generated On: 10 Jun 2021 09:17:27

1/31/21 AND 2/25/21). AFTER SEVERAL WEEKS WITH NO IMPROVEMENT AND GIVEN THE SEVERITY OF HIS LUNG DAMAGE, HIS FAMILY ELECTED TO SIGN A DO NOT RESUSCITATE ORDER. ON 2/25/21 HE DIED FROM THE ARDS WITH ONLY IDENTIFIED CAUSATIVE ORGANISM BEING SARS-COV2.
THE PI DETERMINATION OF CAUSE OF DEATH IS ARDS DUE TO COVID.

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

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Mar 2021 20:15:12

Generated On: 10 Jun 2021 09:17:27

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

Yes

No

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

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication AZELASTINE HCL 0.05%

Prophylaxis Yes
No

Indication ALLERGIES

Dose per administration UNKNOWN

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

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

If route of administration is Other, specify	UNKNOWN
Start date (<i>dd MMM yyyy</i>)	24 SEP 2018
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

If not Ongoing, End date (<i>dd MMM yyyy</i>)	
Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input type="radio"/>

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication BICTEGRAVIR-EMTRICITABINE
-TENOFIVIR ALAFENAMIDE
(BIKTARVY) 50-200-25MG

Prophylaxis Yes
No

Indication HIV

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

	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) 20 APR 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) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication BISACODYL 5MG

Prophylaxis Yes
No

Indication CONSTIPATION

Dose per administration 2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

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 APR 2016

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication CLOTRIMAZOLE 1% CREAM

Prophylaxis Yes
No

Indication UNKNOWN

Dose per administration UNKNOWN

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify UNKNOWN

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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US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

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

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 12 NOV 2018

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication ESCITALOPRAM 5MG

Prophylaxis Yes
No

Indication DEPRESSION

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

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*) 20 APR 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) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication MULTIPLE VITAMIN

Prophylaxis Yes
No

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

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*) 20 APR 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) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication PANTOPRAZOLE 20MG

Prophylaxis Yes
No

Indication ESOPHAGEAL VARICES,
PORTAL HYPERTENSIVE
GASTROPATHY

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

	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) 20 APR 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) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication VALACYCLOVIR HCL 1G

Prophylaxis Yes
No

Indication HSV

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 12 HOURS

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

- 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*) 07 JUN 2017

Start date completely unknown False

Ongoing? Yes
No

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

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication INFLUENZA VACCINE
(FLULAVAL)

Prophylaxis Yes
No

Indication INFLUENZA PROPHYLAXIS

Dose per administration UNKNOWN

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

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

If route of administration is Other, specify _____

Start date (dd MMM yyyy) 02 OCT 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 02 OCT 2020

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication FEVER (COVID-19 SYMPTOMS)

Dose per administration 400

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 (10)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

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

If route of administration is Other, specify _____

Start date (*dd MMM yyyy*) 02 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 03 JAN 2021

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

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication CEFTRIAXONE

Prophylaxis Yes
No

Indication FEVER (RELATED TO COVID-19)

Dose per administration 2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

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 checked="" 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*) 05 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 05 JAN 2021

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

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication REMDESEVIR

Prophylaxis Yes
No

Indication COVID-19

Dose per administration 200

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

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 checked="" 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*) 05 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 05 JAN 2021

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

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication DEXAMETHASONE

Prophylaxis Yes
No

Indication COVID-19

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

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*) 05 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 16 JAN 2021

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

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication REMDESEVIR

Prophylaxis Yes
No

Indication COVID-19

Dose per administration 100

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

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 checked="" 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 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 09 JAN 2021

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

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication LOVENOX

Prophylaxis Yes
No

Indication COVID-19

Dose per administration 40

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

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*) 05 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 11 JAN 2021

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

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication MOTRIN

Prophylaxis Yes
No

Indication COVID-19

Dose per administration 600

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

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

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*) 05 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 05 JAN 2021

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

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication TESSALON PERLE

Prophylaxis Yes
No

Indication COVID-19

Dose per administration 100

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

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

If route of administration is Other, specify	UNKNOWN
Start date (<i>dd MMM yyyy</i>)	06 JAN 2021
Start date completely unknown	False
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, End date (<i>dd MMM yyyy</i>)	11 JAN 2021
Was this medication taken for solicited event?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/> 803 <input type="radio"/> 804 <input checked="" type="radio"/>

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication MELATONIN

Prophylaxis Yes
No

Indication INSOMNIA

Dose per administration 3

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
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

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 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) 09 JAN 2021

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

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication TYLENOL

Prophylaxis Yes
No

Indication COVID-19

Dose per administration 500

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

286 of 2785

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

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*) 19 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 19 JAN 2021

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

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication DEXAMETHASONE

Prophylaxis Yes
No

Indication COVID-19

Dose per administration 6

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)

288 of 2785

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

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 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 15 JAN 2021

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

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

Name of Medication SENNA

Prophylaxis Yes
No

Indication COVID-19

Dose per administration 17.2

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 15 Mar 2021 20:15:11

Generated On: 10 Jun 2021 09:17:27

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*) 05 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) 11 JAN 2021

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

US3702010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Apr 2021 13:11:28

Generated On: 10 Jun 2021 09:17:27

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3702010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 29 Apr 2021 15:29:05

Generated On: 10 Jun 2021 09:17:27

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
20 JAN 2021	HI-FLOW OXYGEN AND BI-LEVEL NON-INVASIVE POSITIVE PRESSURE VENTILATION	Adverse Event	
24 JAN 2021	INTUBATION	Adverse Event	
12 FEB 2021	CARDIOVERSION	Adverse Event	

US3702010

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 15 Mar 2021 20:15:14

Generated On: 10 Jun 2021 09:17:27

Date of dosing discontinuation (dd MMM yyyy) 02 OCT 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

PARTICIPANT REFUSED SECOND INJECTION DUE TO SIDE EFFECTS. HE CONSENTED TO CONTINUE STUDY VISITS.

US3702010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 15 Mar 2021 20:15:14

Generated On: 10 Jun 2021 09:17:27

Date of study discontinuation/completion (*dd MMM yyyy*) 25 FEB 2021

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*) 25 FEB 2021

Was autopsy performed?

Yes

No

Unknown

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 15:29:06

Generated On: 10 Jun 2021 09:17:27

SAEID	USA-US133-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KRISTEN
Investigator's Last Name	MARKS
Site Address: Street	525 EAST 68TH STREET
Site Address: City	NEW YORK
Site Address: State	NY
Site Address: Postal Code	10065
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 15:29:06

Generated On: 10 Jun 2021 09:17:27

SAEID	USA-US133-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KRISTEN
Investigator's Last Name	MARKS
Site Address: Street	525 EAST 68TH STREET
Site Address: City	NEW YORK
Site Address: State	NY
Site Address: Postal Code	10065
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	12/JAN/2021 10:25
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

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 15:29:06

Generated On: 10 Jun 2021 09:17:27

SAEID	USA-US133-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KRISTEN
Investigator's Last Name	MARKS
Site Address: Street	525 EAST 68TH STREET
Site Address: City	NEW YORK
Site Address: State	NY
Site Address: Postal Code	10065
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	28/JAN/2021 19:35
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

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 15:29:06

Generated On: 10 Jun 2021 09:17:27

SAEID	USA-US133-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KRISTEN
Investigator's Last Name	MARKS
Site Address: Street	525 EAST 68TH STREET
Site Address: City	NEW YORK
Site Address: State	NY
Site Address: Postal Code	10065
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	02/FEB/2021 10:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Apr 2021 15:29:06

Generated On: 10 Jun 2021 09:17:27

SAEID	USA-US133-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KRISTEN
Investigator's Last Name	MARKS
Site Address: Street	525 EAST 68TH STREET
Site Address: City	NEW YORK
Site Address: State	NY
Site Address: Postal Code	10065
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	17/FEB/2021 11:10
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 29 Apr 2021 15:29:06

Generated On: 10 Jun 2021 09:17:27

SAEID	USA-US133-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KRISTEN
Investigator's Last Name	MARKS
Site Address: Street	525 EAST 68TH STREET
Site Address: City	NEW YORK
Site Address: State	NY
Site Address: Postal Code	10065
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	15/MAR/2021 11:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	<input checked="" type="checkbox"/> True

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 29 Apr 2021 15:29:06

Generated On: 10 Jun 2021 09:17:27

SAEID	USA-US133-2021-MRNA-1273-P30 1000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KRISTEN
Investigator's Last Name	MARKS
Site Address: Street	525 EAST 68TH STREET
Site Address: City	NEW YORK
Site Address: State	NY
Site Address: Postal Code	10065
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	07/APR/2021 07:11
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.	True

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 29 Apr 2021 15:29:06

Generated On: 10 Jun 2021 09:17:27

SAEID	USA-US133-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KRISTEN
Investigator's Last Name	MARKS
Site Address: Street	525 EAST 68TH STREET
Site Address: City	NEW YORK
Site Address: State	NY
Site Address: Postal Code	10065
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	12/APR/2021 13:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 29 Apr 2021 15:29:06

Generated On: 10 Jun 2021 09:17:27

SAEID	USA-US133-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KRISTEN
Investigator's Last Name	MARKS
Site Address: Street	525 EAST 68TH STREET
Site Address: City	NEW YORK
Site Address: State	NY
Site Address: Postal Code	10065
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	14/APR/2021 10:27
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.	<input checked="" type="checkbox"/> True

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (9)

Data signed: (b) (4) 29 Apr 2021 15:29:06

Generated On: 10 Jun 2021 09:17:27

SAEID	USA-US133-2021-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	KRISTEN
Investigator's Last Name	MARKS
Site Address: Street	525 EAST 68TH STREET
Site Address: City	NEW YORK
Site Address: State	NY
Site Address: Postal Code	10065
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	23/APR/2021 08:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3702010 (Prod: Weill Cornell Chelsea - (CRS))

US3702010

Form: Participant Creation

Generated On: 10 Jun 2021 09:17:27

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'US3702010'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 17:34:52

US3702010

Form: Participant Creation

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Caique Mello (b) (4) (b) (4)	04 Sep 2020 18:50:25

US3702010

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 17:34:53

US3702010

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Clinic (Clinic)'	Caique Mello (b) (4) (b) (4)	04 Sep 2020 18:50:25

US3702010

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'SCRN'	System	04 Sep 2020 18:50:25

US3702010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:27

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered (b) (6) 1946'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 17:34:53

US3702010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:27

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '74'	Jiamin Li (b) (4)	08 Sep 2020 22:38:33

US3702010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:27

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'YEARS'	System	08 Sep 2020 22:38:33

US3702010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:27

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered '74'	System	04 Sep 2020 18:50:46

US3702010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:27

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Male (M)'	Jiamin Li (b) (4)	08 Sep 2020 22:38:33

US3702010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:27

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Jiamin Li (b) (4)	08 Sep 2020 22:38:33

US3702010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:27

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:38:33

US3702010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:27

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:38:33

US3702010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:27

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:38:33

US3702010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:27

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:38:33

US3702010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:27

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:38:33

US3702010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:38:33

US3702010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:27

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:38:33

US3702010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:27

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '1'	Jiamin Li (b) (4)	08 Sep 2020 22:38:33

US3702010

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:17:27

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:38:33

US3702010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '4 Sep 2020'	Caique Mello (b) (4)	04 Sep 2020 18:50:46

US3702010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'Sep 2020'	System	04 Sep 2020 18:50:46

US3702010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered '2020'	System	04 Sep 2020 18:50:46

US3702010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:27

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Amendment 3 (3)'	Caique Mello (b) (4)	04 Sep 2020 18:50:46

US3702010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Caique Mello (b) (4)	04 Sep 2020 18:50:46

US3702010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Caique Mello (b) (4) (b) (4)	04 Sep 2020 18:50:46

US3702010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:27

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Caique Mello (b) (4)	04 Sep 2020 18:50:46

US3702010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:27

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Caique Mello (b) (4)	04 Sep 2020 18:50:46

US3702010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:27

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 17:34:53

US3702010

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:17:27

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered '1'	System	04 Sep 2020 18:50:51

US3702010

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Caique Mello (b) (4) (b) (4)	04 Sep 2020 18:50:51

US3702010

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:17:27

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:38:46

US3702010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatic fibrosis and cirrhosis, PT: Hepatic cirrhosis, LLT: Cirrhosis of liver - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 13:21:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 13:21:46
Data point term sent to Coder	System	08 Sep 2020 22:39:54
User entered 'Cirrhosis of liver due to hepatitis C'	Jiamin Li (b) (4)	08 Sep 2020 22:39:10

US3702010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'un UNK 2007'	Jiamin Li (b) (4)	08 Sep 2020 22:39:10

US3702010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:39:10

US3702010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:39:10

US3702010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:39:10

US3702010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:27

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:39:10

US3702010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'Jan 2007'	System	08 Sep 2020 22:39:10

US3702010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered '2007'	System	08 Sep 2020 22:39:10

US3702010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:39:10

US3702010

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:39:10

US3702010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Retroviral infections, PT: HIV infection, LLT: HIV infection - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 07:30:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 07:30:40
Data point term sent to Coder	System	08 Sep 2020 22:39:53
User entered 'Human immunodeficiency virus infection'	Jiamin Li (b) (4)	08 Sep 2020 22:39:28

US3702010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:39:28

US3702010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '1'	Jiamin Li (b) (4)	08 Sep 2020 22:39:28

US3702010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:39:28

US3702010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:39:28

US3702010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:39:28

US3702010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:39:28

US3702010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:39:28

US3702010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:39:28

US3702010

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:39:28

US3702010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Hepatitis C, LLT: Hepatitis C - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 22:40:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 22:40:59
Data point term sent to Coder	System	08 Sep 2020 22:39:54
User entered 'Hepatitis C'	Jiamin Li (b) (4)	08 Sep 2020 22:39:47

US3702010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'un UNK 2015'	Jiamin Li (b) (4)	08 Sep 2020 22:39:47

US3702010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:39:47

US3702010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:39:47

US3702010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'un UNK 2015'	Jiamin Li (b) (4)	08 Sep 2020 22:39:47

US3702010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:27

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:39:47

US3702010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'Jan 2015'	System	08 Sep 2020 22:39:47

US3702010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered '2015'	System	08 Sep 2020 22:39:47

US3702010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'Jan 2015'	System	08 Sep 2020 22:39:47

US3702010

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered '2015'	System	08 Sep 2020 22:39:47

US3702010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Query 'Per CDM CR: 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. ' canceled (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 22:03:29
User opened query 'Per CDM CR: 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)	09 Oct 2020 17:59:35
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:42:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:42:00
Data point term sent to Coder	System	08 Sep 2020 22:40:54
User entered 'Hypertension'	Jiamin Li (b) (4) (b) (4)	08 Sep 2020 22:39:58

US3702010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'un UNK 2007'	Jiamin Li (b) (4)	08 Sep 2020 22:39:58

US3702010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:39:58

US3702010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:39:58

US3702010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:39:58

US3702010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:27

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:39:58

US3702010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'Jan 2007'	System	08 Sep 2020 22:39:58

US3702010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:27

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered '2007'	System	08 Sep 2020 22:39:58

US3702010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:39:58

US3702010

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:39:58

US3702010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Oesophageal therapeutic procedures, PT: Oesophageal variceal ligation, LLT: Esophageal varices banding - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 09:17:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 09:17:37
Data point term sent to Coder	System	08 Sep 2020 22:40:55
User entered 'Esophageal varices with h/o banding'	Jiamin Li (b) (4)	08 Sep 2020 22:40:12

US3702010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'un UNK 2016'	Jiamin Li (b) (4)	08 Sep 2020 22:40:12

US3702010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:40:12

US3702010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:40:12

US3702010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:40:12

US3702010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:27

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:40:12

US3702010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'Jan 2016'	System	08 Sep 2020 22:40:12

US3702010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered '2016'	System	08 Sep 2020 22:40:12

US3702010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:40:12

US3702010

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:40:12

US3702010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as SOC: Gastrointestinal disorders, HLGHT: Gastrointestinal haemorrhages NEC, HLT: Gastric and oesophageal haemorrhages, PT: Portal hypertensive gastropathy, LLT: Portal hypertensive gastropathy - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 22:41:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 22:41:59
Data point term sent to Coder	System	08 Sep 2020 22:40:55
User entered 'Portal hypertensive gastropathy'	Jiamin Li (b) (4)	08 Sep 2020 22:40:33

US3702010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '10 Oct 2019'	Jiamin Li (b) (4)	08 Sep 2020 22:40:33

US3702010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:40:33

US3702010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:40:33

US3702010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:40:33

US3702010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:27

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:40:33

US3702010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'Oct 2019'	System	08 Sep 2020 22:40:33

US3702010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered '2019'	System	08 Sep 2020 22:40:33

US3702010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:40:33

US3702010

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:40:33

US3702010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin and subcutaneous tissue disorders NEC, HLT: Lipodystrophies, PT: Lipodystrophy acquired, LLT: Lipodystrophy - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 13:35:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 13:35:57
Data point term sent to Coder	System	08 Sep 2020 22:40:56
User entered 'Lipodystrophy due to AIDS antiretroviral therapy'	Jiamin Li (b) (4)	08 Sep 2020 22:40:49

US3702010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'un UNK 2007'	Jiamin Li (b) (4)	08 Sep 2020 22:40:49

US3702010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:40:49

US3702010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:40:49

US3702010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:40:49

US3702010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:27

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:40:49

US3702010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'Jan 2007'	System	08 Sep 2020 22:40:49

US3702010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered '2007'	System	08 Sep 2020 22:40:49

US3702010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:40:49

US3702010

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:40:49

US3702010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Insulin resistance, LLT: Insulin resistance - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 22:43:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Sep 2020 22:43:02
Data point term sent to Coder	System	08 Sep 2020 22:41:58
User entered 'Insulin resistance'	Jiamin Li (b) (4)	08 Sep 2020 22:40:58

US3702010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:40:58

US3702010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '1'	Jiamin Li (b) (4)	08 Sep 2020 22:40:58

US3702010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:40:58

US3702010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:40:58

US3702010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:27

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:40:58

US3702010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:40:58

US3702010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:40:58

US3702010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:40:58

US3702010

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:40:58

US3702010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:17:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 22:43:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 22:43:02
Data point term sent to Coder	System	08 Sep 2020 22:41:58
User entered 'Herpes simplex'	Jiamin Li (b) (4)	08 Sep 2020 22:41:07

US3702010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'un UNK 2000'	Jiamin Li (b) (4)	08 Sep 2020 22:41:07

US3702010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:41:07

US3702010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:17:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:41:07

US3702010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:41:07

US3702010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:17:27

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:41:07

US3702010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:17:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'Jan 2000'	System	08 Sep 2020 22:41:07

US3702010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered '2000'	System	08 Sep 2020 22:41:07

US3702010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:41:07

US3702010

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:41:07

US3702010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:17:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Colonic polyp - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 22:43:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 22:43:02
Data point term sent to Coder	System	08 Sep 2020 22:41:58
User entered 'Colonic polyps'	Jiamin Li (b) (4)	08 Sep 2020 22:41:24

US3702010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'un UNK 2013'	Jiamin Li (b) (4)	08 Sep 2020 22:41:24

US3702010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:17:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:41:24

US3702010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:17:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:41:24

US3702010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:41:24

US3702010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:17:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '1'	Jiamin Li (b) (4)	08 Sep 2020 22:41:24

US3702010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:17:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'Jan 2013'	System	08 Sep 2020 22:41:24

US3702010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered '2013'	System	08 Sep 2020 22:41:24

US3702010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:41:24

US3702010

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:41:24

US3702010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:17:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as SOC: Reproductive system and breast disorders, HLG: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 11:57:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 11:57:47
Data point term sent to Coder	System	08 Sep 2020 22:41:59
User entered 'Benign prostatic hyperplasia associated with nocturia'	Jiamin Li (b) (4)	08 Sep 2020 22:41:49

US3702010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'un UNK 2010'	Jiamin Li (b) (4)	08 Sep 2020 22:41:49

US3702010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:41:49

US3702010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:17:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:41:49

US3702010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:41:49

US3702010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:17:27

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:41:49

US3702010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:17:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'Jan 2010'	System	08 Sep 2020 22:41:49

US3702010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered '2010'	System	08 Sep 2020 22:41:49

US3702010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:41:49

US3702010

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:41:49

US3702010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:17:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as SOC: Cardiac disorders, HLT: Cardiac conduction disorders, PT: Bundle branch block right, LLT: Right bundle branch block - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 09:24:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 09:24:40
Data point term sent to Coder	System	08 Sep 2020 22:42:59
User entered 'Exercise-induced right bundle branch block during exercise stress test - asymptomatic'	Jiamin Li (b) (4)	08 Sep 2020 22:42:20

US3702010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'un UNK 2012'	Jiamin Li (b) (4)	08 Sep 2020 22:42:20

US3702010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:42:20

US3702010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:17:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:42:20

US3702010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:42:20

US3702010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:17:27

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:42:20

US3702010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:17:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'Jan 2012'	System	08 Sep 2020 22:42:20

US3702010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered '2012'	System	08 Sep 2020 22:42:20

US3702010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:42:20

US3702010

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	08 Sep 2020 22:42:20

US3702010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:17:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	22 Dec 2020 00:09:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Dec 2020 00:09:35
Data point term sent to Coder	System	22 Dec 2020 00:08:39
User entered 'Constipation'	Jiamin Li (b) (4)	22 Dec 2020 00:08:13

US3702010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:08:13

US3702010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '1'	Jiamin Li (b) (4)	22 Dec 2020 00:08:13

US3702010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:17:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Dec 2020 00:08:13

US3702010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:08:13

US3702010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:17:27

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	22 Dec 2020 00:08:13

US3702010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:17:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	22 Dec 2020 00:08:13

US3702010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	22 Dec 2020 00:08:13

US3702010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	22 Dec 2020 00:08:13

US3702010

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	22 Dec 2020 00:08:13

US3702010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:17:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 17:29:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 17:29:39
Data point term sent to Coder	System	09 Mar 2021 17:13:09
User entered 'Depression'	Jiamin Li (b) (4)	09 Mar 2021 17:12:48

US3702010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'un UNK 2000'	Jiamin Li (b) (4)	09 Mar 2021 17:12:48

US3702010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	09 Mar 2021 17:12:48

US3702010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:17:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	09 Mar 2021 17:12:48

US3702010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	09 Mar 2021 17:12:48

US3702010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:17:27

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	09 Mar 2021 17:12:48

US3702010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:17:27

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'Jan 2000'	System	09 Mar 2021 17:12:48

US3702010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered '2000'	System	09 Mar 2021 17:12:48

US3702010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	09 Mar 2021 17:12:48

US3702010

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered empty.	System	09 Mar 2021 17:12:48

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:48:27

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '04 Sep 2020'	Jiamin Li (b) (4)	08 Sep 2020 22:48:27

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '13:43'	Jiamin Li (b) (4)	08 Sep 2020 22:48:27

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered '04 Sep 2020 13:43'	System	08 Sep 2020 22:48:27

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '164' cm	Jiamin Li (b) (4)	08 Sep 2020 22:48:27
DataPoint set to visible.	(b) (4) System	04 Sep 2020 18:50:51

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '92.7' kg	Jiamin Li (b) (4)	08 Sep 2020 22:48:27
DataPoint set to visible.	(b) (4) System	04 Sep 2020 18:50:51

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered '34.46609'	System	08 Sep 2020 22:48:27
DataPoint set to visible.	System	04 Sep 2020 18:50:51

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'kg/m2'	System	08 Sep 2020 22:48:27
DataPoint set to visible.	System	04 Sep 2020 18:50:51

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	08 Sep 2020 22:48:27

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:48:27

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:48:27

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	08 Sep 2020 22:48:27

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'bpm'	System	08 Sep 2020 22:48:27

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	08 Sep 2020 22:48:27

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'breaths/min'	System	08 Sep 2020 22:48:27

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	08 Sep 2020 22:48:27

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'mmHg'	System	08 Sep 2020 22:48:27

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	08 Sep 2020 22:48:27

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User entered 'mmHg'	System	08 Sep 2020 22:48:27

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59

US3702010

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59

US3702010

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:27

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:47:23

US3702010

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '04 Sep 2020'	Jiamin Li (b) (4)	08 Sep 2020 22:47:23

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

[Manufacturing & Production Operations](#) with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

[Resides in Multi-family dwelling](#) (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '1'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '1'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:17:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:54:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Uses public transportation'	Jiamin Li (b) (4)	08 Sep 2020 22:50:21

US3702010

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:50:29

US3702010

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '04 Sep 2020'	Jiamin Li (b) (4)	08 Sep 2020 22:50:29

US3702010

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Clinic (Clinic)'	Jiamin Li (b) (4)	08 Sep 2020 22:50:29

US3702010

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered 'VISIT1'	System	08 Sep 2020 22:50:29

US3702010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:31
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '04 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 18:04:24

US3702010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:31
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '188150'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 18:04:24

US3702010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:31
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 18:04:24

US3702010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:17:27

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:31
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:50:42

US3702010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:17:27

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:31
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:50:42

US3702010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:31
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:50:42

US3702010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:17:27

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:31
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	08 Sep 2020 22:50:42

US3702010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:17:27

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:31
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
Query 'Per CDM: Please note that at-risk factor is checked as "Yes", but subject is not enrolled in the at-risk cohort, please clarify or reconcile' canceled (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 14:12:26
User opened query 'Per CDM: Please note that at-risk factor is checked as "Yes", but subject is not enrolled in the at-risk cohort, please clarify or reconcile' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 21:02:07
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:50:42

US3702010

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:17:27

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:31
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Yes (Y)'	Jiamin Li (b) (4)	21 Sep 2020 16:15:09
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:26:55
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:26:53

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:17:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:17:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:17:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:17:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User accepted default value 'Pre-Dose (PREDOSE)'	Jiamin Li (b) (4) (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '04 Sep 2020'	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '13:43'	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered '04 Sep 2020 13:43'	System	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '37.2' C	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Other (Other)'	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Temporal'	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '76'	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered 'bpm'	System	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '14'	Jiamin Li (b) (4) (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered 'breaths/min'	System	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '118'	Jiamin Li (b) (4) (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered 'mmHg'	System	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '75'	Jiamin Li (b) (4) (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered 'mmHg'	System	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:17:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:17:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User accepted default value 'Post-Dose (POSTDOSE)'	Jiamin Li (b) (4) (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '04 Sep 2020'	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '15:52'	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered '04 Sep 2020 15:52'	System	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '36.1' C	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Oral (Oral)'	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '61'	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered 'bpm'	System	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '16'	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered 'breaths/min'	System	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '147'	Jiamin Li (b) (4) (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered 'mmHg'	System	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '77'	Jiamin Li (b) (4)	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:40
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered 'mmHg'	System	08 Sep 2020 22:49:27

US3702010

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:52
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:49:33

US3702010

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:22:52
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:49:33

US3702010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Caique Mello (b) (4) (b) (4)	04 Sep 2020 18:51:29

US3702010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Caique Mello (b) (4) (b) (4)	04 Sep 2020 18:51:29

US3702010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

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)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Caique Mello (b) (4)	04 Sep 2020 18:51:29

US3702010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 18:51:29

US3702010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '4 Sep 2020'	Caique Mello (b) (4) (b) (4)	04 Sep 2020 18:51:29

US3702010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '14:21'	Caique Mello (b) (4) (b) (4)	04 Sep 2020 18:51:29

US3702010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered '4 Sep 2020 14:21'	System	04 Sep 2020 18:51:29

US3702010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Left Arm (LEFT ARM)'	Caique Mello (b) (4) (b) (4)	04 Sep 2020 18:51:29

US3702010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered 'ONCE'	System	04 Sep 2020 18:51:29

US3702010

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:00
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 18:51:29

US3702010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	11 Sep 2020 16:31:12

US3702010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 16:31:27
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		11 Sep 2020 16:31:27
User closed query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	11 Sep 2020 16:31:27
User closed query 'The Collection Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		11 Sep 2020 16:31:27
User entered '04 Sep 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	11 Sep 2020 16:31:27
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 16:31:12
User opened query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	11 Sep 2020 16:31:12
User opened query 'The Collection Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 16:31:12
User entered '03 Sep 2020'	Jiamin Li (b) (4)	11 Sep 2020 16:31:12

US3702010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '13:56'	Jiamin Li (b) (4) (b) (4)	11 Sep 2020 16:31:12

US3702010

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:13
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered '04 Sep 2020 13:56'	System	11 Sep 2020 16:31:27
User entered '03 Sep 2020 13:56'	System	11 Sep 2020 16:31:12

US3702010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:17:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '04 Sep 2020'	Jiamin Li (b) (4)	08 Sep 2020 22:55:43

US3702010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:17:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jiamin Li (b) (4) (b) (4)	08 Sep 2020 22:55:43

US3702010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:17:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:55:43

US3702010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:17:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '14:20'	Jiamin Li (b) (4) (b) (4)	08 Sep 2020 22:55:43

US3702010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:17:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered '04 Sep 2020 14:20'	System	08 Sep 2020 22:55:43

US3702010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:17:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jiamin Li (b) (4)	08 Sep 2020 22:55:43

US3702010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:17:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:55:43

US3702010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:17:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4) (b) (4)	08 Sep 2020 22:55:43

US3702010

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:17:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:23:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered empty.	System	08 Sep 2020 22:55:43

US3702010

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:24:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:55:58

US3702010

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:17:06
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:24:36
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered '1'	System	08 Sep 2020 22:55:58

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T15:00:06', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '3eec73f9-6d9b-4616-9410-fc16986b21ab'	System	04 Sep 2020 19:02:34
User entered 'Yes (Y)'	System	04 Sep 2020 19:02:34

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T15:01:58', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '3eec73f9-6d9b-4616-9410-fc16986b21ab'	System	04 Sep 2020 19:02:34
User entered '97.0'	System	04 Sep 2020 19:02:34

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T15:02:24', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '3eec73f9-6d9b-4616-9410-fc16986b21ab'	System	04 Sep 2020 19:02:34
User entered 'No (N)'	System	04 Sep 2020 19:02:34

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T15:02:30', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '3eec73f9-6d9b-4616-9410-fc16986b21ab'	System	04 Sep 2020 19:02:34
User entered '04 Sep 2020 15:02'	System	04 Sep 2020 19:02:34

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '04 Sep 2020 14:41'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '04 Sep 2020 17:11'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T21:42:29', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'e075726e-25f8-4a3b-ab5b-90de509b12dd'	System	05 Sep 2020 01:42:47
User entered 'Yes (Y)'	System	05 Sep 2020 01:42:47

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T21:41:58', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'e075726e-25f8-4a3b-ab5b-90de509b12dd'	System	05 Sep 2020 01:42:47
User entered '97.2'	System	05 Sep 2020 01:42:47

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T21:42:07', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'e075726e-25f8-4a3b-ab5b-90de509b12dd'	System	05 Sep 2020 01:42:47
User entered 'No (N)'	System	05 Sep 2020 01:42:47

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T21:42:44', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'e075726e-25f8-4a3b-ab5b-90de509b12dd'	System	05 Sep 2020 01:42:47
User entered '04 Sep 2020 21:42'	System	05 Sep 2020 01:42:47

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '04 Sep 2020 18:06'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 2'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-05T20:17:21', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '64e2be0b-095e-4b47-8555-628d4aeaf388'	System	06 Sep 2020 00:18:09
User entered 'Yes (Y)'	System	06 Sep 2020 00:18:09

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-05T20:17:41', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '64e2be0b-095e-4b47-8555-628d4aeaf388'	System	06 Sep 2020 00:18:09
User entered '98.3'	System	06 Sep 2020 00:18:09

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-05T20:17:50', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '64e2be0b-095e-4b47-8555-628d4aeaf388'	System	06 Sep 2020 00:18:09
User entered 'No (N)'	System	06 Sep 2020 00:18:09

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-05T20:18:03', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '64e2be0b-095e-4b47-8555-628d4aeaf388'	System	06 Sep 2020 00:18:09
User entered '05 Sep 2020 20:18'	System	06 Sep 2020 00:18:09

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 3'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-06T21:56:15', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'd4747717-b2c5-4029-9742-692fe79c9d2a'	System	07 Sep 2020 01:57:15
User entered 'Yes (Y)'	System	07 Sep 2020 01:57:15

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-06T21:56:49', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'd4747717-b2c5-4029-9742-692fe79c9d2a'	System	07 Sep 2020 01:57:15
User entered '97.6'	System	07 Sep 2020 01:57:15

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-06T21:56:58', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'd4747717-b2c5-4029-9742-692fe79c9d2a'	System	07 Sep 2020 01:57:15
User entered 'No (N)'	System	07 Sep 2020 01:57:15

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-06T21:57:10', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'd4747717-b2c5-4029-9742-692fe79c9d2a'	System	07 Sep 2020 01:57:15
User entered '06 Sep 2020 21:57'	System	07 Sep 2020 01:57:15

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 4'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-07T21:58:38', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '8dde919f-2660-4769-891c-d2f09c0851f8'	System	08 Sep 2020 01:59:26
User entered 'Yes (Y)'	System	08 Sep 2020 01:59:26

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-07T21:58:48', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '8dde919f-2660-4769-891c-d2f09c0851f8'	System	08 Sep 2020 01:59:26
User entered '97.2'	System	08 Sep 2020 01:59:26

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-07T21:58:59', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '8dde919f-2660-4769-891c-d2f09c0851f8'	System	08 Sep 2020 01:59:26
User entered 'No (N)'	System	08 Sep 2020 01:59:26

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-07T21:59:19', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '8dde919f-2660-4769-891c-d2f09c0851f8'	System	08 Sep 2020 01:59:26
User entered '07 Sep 2020 21:59'	System	08 Sep 2020 01:59:26

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 5'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-09T01:04:53', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '0029db29-6aad-4a0f-ad17-e4de77a2b264'	System	09 Sep 2020 05:05:21
User entered 'Yes (Y)'	System	09 Sep 2020 05:05:21

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-09T01:05:02', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '0029db29-6aad-4a0f-ad17-e4de77a2b264' User entered '97.3'	System	09 Sep 2020 05:05:21
	System	09 Sep 2020 05:05:21

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-09T01:05:09', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '0029db29-6aad-4a0f-ad17-e4de77a2b264'	System	09 Sep 2020 05:05:21
User entered 'No (N)'	System	09 Sep 2020 05:05:21

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-09T01:05:13', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '0029db29-6aad-4a0f-ad17-e4de77a2b264'	System	09 Sep 2020 05:05:21
User entered '09 Sep 2020 01:05'	System	09 Sep 2020 05:05:21

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 6'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 7'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T15:02:42', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'c5d3b809-7b44-4646-9d9b-1f4abaf29328'	System	04 Sep 2020 19:03:11
User entered 'None (1)'	System	04 Sep 2020 19:03:11

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T15:02:47', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'c5d3b809-7b44-4646-9d9b-1f4abaf29328'	System	04 Sep 2020 19:03:11
User entered 'No (N)'	System	04 Sep 2020 19:03:11

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T15:02:53', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'c5d3b809-7b44-4646-9d9b-1f4abaf29328'	System	04 Sep 2020 19:03:11
User entered 'No (N)'	System	04 Sep 2020 19:03:11

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T15:02:58', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'c5d3b809-7b44-4646-9d9b-1f4abaf29328'	System	04 Sep 2020 19:03:11
User entered 'None (1)'	System	04 Sep 2020 19:03:11

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T15:03:01', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'c5d3b809-7b44-4646-9d9b-1f4abaf29328'	System	04 Sep 2020 19:03:11
User entered '04 Sep 2020 15:03'	System	04 Sep 2020 19:03:11

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '04 Sep 2020 14:41'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '04 Sep 2020 17:11'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '04 Sep 2020 18:06'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 2'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-05T20:18:52', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '531abb7c-1eed-4378-9c5d-daa9efdcfa77'	System	06 Sep 2020 00:20:24
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 00:20:24

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-05T20:19:13', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '531abb7c-1eed-4378-9c5d-daa9efdcfa77'	System	06 Sep 2020 00:20:24
User entered 'No (N)'	System	06 Sep 2020 00:20:24

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-05T20:19:21', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '531abb7c-1eed-4378-9c5d-daa9efdcfa77'	System	06 Sep 2020 00:20:24
User entered 'No (N)'	System	06 Sep 2020 00:20:24

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-05T20:20:01', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '531abb7c-1eed-4378-9c5d-daa9efdcfa77'	System	06 Sep 2020 00:20:24
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 00:20:24

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-05T20:20:20', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '531abb7c-1eed-4378-9c5d-daa9efdcfa77'	System	06 Sep 2020 00:20:24
User entered '05 Sep 2020 20:20'	System	06 Sep 2020 00:20:24

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 3'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-06T21:57:54', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'dc5229db-769e-4392-8ddd-ae5bd5585ce'	System	07 Sep 2020 02:03:05
User entered 'None (1)'	System	07 Sep 2020 02:03:05

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-06T21:58:11', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'dc5229db-769e-4392-8ddd-ae5bd5585ce'	System	07 Sep 2020 02:03:05
User entered 'Yes (Y)'	System	07 Sep 2020 02:03:05

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:27

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-06T22:02:10', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'dc5229db-769e-4392-8ddd-ae5bd5585ce'	System	07 Sep 2020 02:03:05
User entered '33'	System	07 Sep 2020 02:03:05

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-06T22:02:19', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'dc5229db-769e-4392-8ddd-ae5bd5585ce'	System	07 Sep 2020 02:03:05
User entered 'No (N)'	System	07 Sep 2020 02:03:05

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-06T22:02:42', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'dc5229db-769e-4392-8ddd-ae5bd5585ce'	System	07 Sep 2020 02:03:05
User entered 'None (1)'	System	07 Sep 2020 02:03:05

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-06T22:03:00', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'dc5229db-769e-4392-8ddd-ae5bd5585ce'	System	07 Sep 2020 02:03:05
User entered '06 Sep 2020 22:03'	System	07 Sep 2020 02:03:05

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 4'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-07T21:59:53', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'eb516675-a507-437e-b4b7-b420733b5383'	System	08 Sep 2020 02:00:30
User entered 'Does not interfere with activity (2)'	System	08 Sep 2020 02:00:30

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-07T22:00:00', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'eb516675-a507-437e-b4b7-b420733b5383'	System	08 Sep 2020 02:00:30
User entered 'No (N)'	System	08 Sep 2020 02:00:30

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-07T22:00:11', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'eb516675-a507-437e-b4b7-b420733b5383'	System	08 Sep 2020 02:00:30
User entered 'No (N)'	System	08 Sep 2020 02:00:30

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-07T22:00:17', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'eb516675-a507-437e-b4b7-b420733b5383'	System	08 Sep 2020 02:00:30
User entered 'None (1)'	System	08 Sep 2020 02:00:30

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-07T22:00:24', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'eb516675-a507-437e-b4b7-b420733b5383'	System	08 Sep 2020 02:00:30
User entered '07 Sep 2020 22:00'	System	08 Sep 2020 02:00:30

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 5'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-09T01:05:31', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'd57f5c50-383a-4aa1-ba08-260aa9c835a5'	System	09 Sep 2020 05:06:06
User entered 'None (1)'	System	09 Sep 2020 05:06:06

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-09T01:05:37', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'd57f5c50-383a-4aa1-ba08-260aa9c835a5'	System	09 Sep 2020 05:06:06
User entered 'No (N)'	System	09 Sep 2020 05:06:06

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-09T01:05:45', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'd57f5c50-383a-4aa1-ba08-260aa9c835a5'	System	09 Sep 2020 05:06:06
User entered 'No (N)'	System	09 Sep 2020 05:06:06

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-09T01:05:53', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'd57f5c50-383a-4aa1-ba08-260aa9c835a5'	System	09 Sep 2020 05:06:06
User entered 'None (1)'	System	09 Sep 2020 05:06:06

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-09T01:05:59', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'd57f5c50-383a-4aa1-ba08-260aa9c835a5'	System	09 Sep 2020 05:06:06
User entered '09 Sep 2020 01:05'	System	09 Sep 2020 05:06:06

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 6'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:27

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:27

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 7'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:27

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:27

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:27

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T15:03:08', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'eb466c4f-f218-4614-9775-c5dc33a1683d'	System	04 Sep 2020 19:03:40
User entered 'None (0)'	System	04 Sep 2020 19:03:40

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T15:03:12', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'eb466c4f-f218-4614-9775-c5dc33a1683d'	System	04 Sep 2020 19:03:40
User entered 'None (0)'	System	04 Sep 2020 19:03:40

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T15:03:17', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'eb466c4f-f218-4614-9775-c5dc33a1683d'	System	04 Sep 2020 19:03:40
User entered 'None (0)'	System	04 Sep 2020 19:03:40

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T15:03:19', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'eb466c4f-f218-4614-9775-c5dc33a1683d'	System	04 Sep 2020 19:03:40
User entered 'None (0)'	System	04 Sep 2020 19:03:40

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T15:03:22', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'eb466c4f-f218-4614-9775-c5dc33a1683d'	System	04 Sep 2020 19:03:40
User entered 'None (0)'	System	04 Sep 2020 19:03:40

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T15:03:27', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'eb466c4f-f218-4614-9775-c5dc33a1683d'	System	04 Sep 2020 19:03:40
User entered 'None (0)'	System	04 Sep 2020 19:03:40

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T15:03:33', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'eb466c4f-f218-4614-9775-c5dc33a1683d'	System	04 Sep 2020 19:03:40
User entered 'No (N)'	System	04 Sep 2020 19:03:40

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-04T15:03:36', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'eb466c4f-f218-4614-9775-c5dc33a1683d'	System	04 Sep 2020 19:03:40
User entered '04 Sep 2020 15:03'	System	04 Sep 2020 19:03:40

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '04 Sep 2020 14:41'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '04 Sep 2020 17:11'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '04 Sep 2020 18:06'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 2'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-05T20:20:41', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '96ee0457-c899-4674-9f75-adf3ad1a30ac'	System	06 Sep 2020 00:22:05
User entered 'None (0)'	System	06 Sep 2020 00:22:05

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-05T20:20:55', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '96ee0457-c899-4674-9f75-adf3ad1a30ac'	System	06 Sep 2020 00:22:05
User entered 'Significant; prevents daily activity (3)'	System	06 Sep 2020 00:22:05

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-05T20:21:06', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '96ee0457-c899-4674-9f75-adf3ad1a30ac'	System	06 Sep 2020 00:22:05
User entered 'None (0)'	System	06 Sep 2020 00:22:05

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-05T20:21:24', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '96ee0457-c899-4674-9f75-adf3ad1a30ac'	System	06 Sep 2020 00:22:05
User entered 'None (0)'	System	06 Sep 2020 00:22:05

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-05T20:21:36', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '96ee0457-c899-4674-9f75-adf3ad1a30ac'	System	06 Sep 2020 00:22:05
User entered 'None (0)'	System	06 Sep 2020 00:22:05

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-05T20:21:42', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '96ee0457-c899-4674-9f75-adf3ad1a30ac'	System	06 Sep 2020 00:22:05
User entered 'None (0)'	System	06 Sep 2020 00:22:05

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-05T20:21:52', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '96ee0457-c899-4674-9f75-adf3ad1a30ac'	System	06 Sep 2020 00:22:05
User entered 'No (N)'	System	06 Sep 2020 00:22:05

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-05T20:22:00', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '96ee0457-c899-4674-9f75-adf3ad1a30ac'	System	06 Sep 2020 00:22:05
User entered '05 Sep 2020 20:22'	System	06 Sep 2020 00:22:05

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 3'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-06T22:03:15', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '880522fb-bc9d-4691-ba34-05e67d7995a2'	System	07 Sep 2020 02:04:33
User entered 'None (0)'	System	07 Sep 2020 02:04:33

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-06T22:03:35', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '880522fb-bc9d-4691-ba34-05e67d7995a2'	System	07 Sep 2020 02:04:33
User entered 'Significant; prevents daily activity (3)'	System	07 Sep 2020 02:04:33

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-06T22:03:47', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '880522fb-bc9d-4691-ba34-05e67d7995a2'	System	07 Sep 2020 02:04:33
User entered 'None (0)'	System	07 Sep 2020 02:04:33

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-06T22:03:56', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '880522fb-bc9d-4691-ba34-05e67d7995a2'	System	07 Sep 2020 02:04:33
User entered 'None (0)'	System	07 Sep 2020 02:04:33

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-06T22:04:03', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '880522fb-bc9d-4691-ba34-05e67d7995a2'	System	07 Sep 2020 02:04:33
User entered 'None (0)'	System	07 Sep 2020 02:04:33

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-06T22:04:10', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '880522fb-bc9d-4691-ba34-05e67d7995a2'	System	07 Sep 2020 02:04:33
User entered 'None (0)'	System	07 Sep 2020 02:04:33

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-06T22:04:22', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '880522fb-bc9d-4691-ba34-05e67d7995a2'	System	07 Sep 2020 02:04:33
User entered 'No (N)'	System	07 Sep 2020 02:04:33

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-06T22:04:29', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: '880522fb-bc9d-4691-ba34-05e67d7995a2'	System	07 Sep 2020 02:04:33
User entered '06 Sep 2020 22:04'	System	07 Sep 2020 02:04:33

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 4'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-07T22:00:50', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'dd1382f0-1ad8-4866-a74b-56d437939eed'	System	08 Sep 2020 02:03:53
User entered 'None (0)'	System	08 Sep 2020 02:03:53

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-07T22:01:25', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'dd1382f0-1ad8-4866-a74b-56d437939eed'	System	08 Sep 2020 02:03:53
User entered 'Some interference with activity (2)'	System	08 Sep 2020 02:03:53

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-07T22:01:56', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'dd1382f0-1ad8-4866-a74b-56d437939eed'	System	08 Sep 2020 02:03:53
User entered 'None (0)'	System	08 Sep 2020 02:03:53

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-07T22:02:10', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'dd1382f0-1ad8-4866-a74b-56d437939eed'	System	08 Sep 2020 02:03:53
User entered 'None (0)'	System	08 Sep 2020 02:03:53

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-07T22:03:22', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'dd1382f0-1ad8-4866-a74b-56d437939eed'	System	08 Sep 2020 02:03:53
User entered 'None (0)'	System	08 Sep 2020 02:03:53

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-07T22:03:32', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'dd1382f0-1ad8-4866-a74b-56d437939eed'	System	08 Sep 2020 02:03:53
User entered 'None (0)'	System	08 Sep 2020 02:03:53

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-07T22:03:43', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'dd1382f0-1ad8-4866-a74b-56d437939eed'	System	08 Sep 2020 02:03:53
User entered 'No (N)'	System	08 Sep 2020 02:03:53

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2f58e4e21f726b7d)', Time: '2020-09-07T22:03:50', User OID: 'PatientReportedOutcome (US3702010)', ODM File OID: 'dd1382f0-1ad8-4866-a74b-56d437939eed'	System	08 Sep 2020 02:03:53
User entered '07 Sep 2020 22:03'	System	08 Sep 2020 02:03:53

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 5'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 6'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 7'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 18:51:29

US3702010

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:17:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 01:48:22
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:36
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:24:45
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	28 Sep 2020 21:26:26

US3702010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:36
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:24:45
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '11 Sep 2020'	Jiamin Li (b) (4)	28 Sep 2020 21:26:26

US3702010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:36
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:24:45
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	28 Sep 2020 21:26:26

US3702010

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:36
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:24:45
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	28 Sep 2020 21:26:26

US3702010

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:36
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:24:52
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	28 Sep 2020 17:25:34

US3702010

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:07:36
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:24:52
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered '1'	System	28 Sep 2020 17:25:34

US3702010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:25:06
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	28 Sep 2020 21:27:06

US3702010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:25:06
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '21 Sep 2020'	Jiamin Li (b) (4)	28 Sep 2020 21:27:06

US3702010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:25:06
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	28 Sep 2020 21:27:06

US3702010

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:25:06
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	28 Sep 2020 21:27:06

US3702010

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:25:12
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	28 Sep 2020 17:25:39

US3702010

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:19:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 18:25:12
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:21:02
User entered '1'	System	28 Sep 2020 17:25:39

US3702010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:57
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	28 Sep 2020 21:26:47

US3702010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:57
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '28 Sep 2020'	Jiamin Li (b) (4)	28 Sep 2020 21:26:47

US3702010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:57
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	28 Sep 2020 21:26:47

US3702010

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:57
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	28 Sep 2020 21:26:47

US3702010

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:57
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	28 Sep 2020 17:25:47

US3702010

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:57
User entered '1'	System	28 Sep 2020 17:25:47

US3702010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Yes (Y)'	Jiamin Li (b) (4)	13 Oct 2020 03:01:03

US3702010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2OCT2020 is reported under Visit 2 Day 29visit 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)	22 Dec 2020 18:02:17
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2OCT2020 is reported under Visit 2 Day 29visit 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 'Updated' (Site from DM).	Jiamin Li (b) (4)	22 Dec 2020 00:13:15
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2OCT2020 is reported under Visit 2 Day 29visit 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)	21 Oct 2020 14:36:29
User entered '02 Oct 2020'	Jiamin Li (b) (4)	13 Oct 2020 03:01:03

US3702010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Clinic (Clinic)'	Jiamin Li (b) (4)	13 Oct 2020 03:01:03

US3702010

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User entered 'VISIT2'	System	13 Oct 2020 03:01:03

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User accepted default value 'Pre-Dose (PREDOSE)'	Jiamin Li (b) (4) (b) (4)	28 Oct 2020 15:45:59

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User closed query 'per CDM: data is required, please input applicable data into the proper fields' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 13:52:09
Query 'per CDM: data is required, please input applicable data into the proper fields' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	28 Oct 2020 15:46:07
User entered 'Yes (Y)'	Jiamin Li (b) (4)	28 Oct 2020 15:45:59
User opened query 'per CDM: data is required, please input applicable data into the proper fields' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 15:58:07

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '02 Oct 2020'	Jiamin Li (b) (4)	28 Oct 2020 15:45:59

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '18:18'	Jiamin Li (b) (4)	28 Oct 2020 15:45:59

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User entered '02 Oct 2020 18:18'	System	28 Oct 2020 15:45:59

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '37.2' C	Jiamin Li (b) (4)	28 Oct 2020 15:45:59

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Other (Other)'	Jiamin Li (b) (4)	28 Oct 2020 15:45:59

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Temporal'	Jiamin Li (b) (4)	28 Oct 2020 15:45:59

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '63'	Jiamin Li (b) (4)	28 Oct 2020 15:45:59

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User entered 'bpm'	System	28 Oct 2020 15:45:59

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 13:52:13
Query 'Data is required. Please provide.' answered with 'Not evaluated' (Site from System).	Jiamin Li (b) (4)	28 Oct 2020 15:46:13
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Oct 2020 15:45:59
User entered empty.	Jiamin Li (b) (4)	28 Oct 2020 15:45:59

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User entered empty.	System	28 Oct 2020 15:45:59

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '157'	Jiamin Li (b) (4)	28 Oct 2020 15:45:59

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User entered 'mmHg'	System	28 Oct 2020 15:45:59

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '67'	Jiamin Li (b) (4)	28 Oct 2020 15:45:59

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:17:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User entered 'mmHg'	System	28 Oct 2020 15:45:59

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User accepted default value 'Post-Dose (POSTDOSE)'	Jiamin Li (b) (4) (b) (4)	22 Dec 2020 00:13:26

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User closed query 'per CDM RQ: response noted, however please use drop down menu to enter no if vital signs were not assessed' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 15:46:16
Query 'per CDM RQ: response noted, however please use drop down menu to enter no if vital signs were not assessed' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	22 Dec 2020 00:13:30
User entered 'No (N)'	Jiamin Li (b) (4)	22 Dec 2020 00:13:26
User opened query 'per CDM RQ: response noted, however please use drop down menu to enter no if vital signs were not assessed' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 13:52:53
User closed query 'per CDM: data is required, please input applicable data into the proper fields ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 13:52:53
Query 'per CDM: data is required, please input applicable data into the proper fields ' answered with 'Not evaluated since participant did not receive second dose.' (Site from DM).	Jiamin Li (b) (4)	28 Oct 2020 15:46:30
User opened query 'per CDM: data is required, please input applicable data into the proper fields ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 15:58:17

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:13:26

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:13:26

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User entered empty.	System	22 Dec 2020 00:13:26

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:13:26

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:13:26

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:13:26

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:13:26

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User entered empty.	System	22 Dec 2020 00:13:26

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:13:26

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User entered empty.	System	22 Dec 2020 00:13:26

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:13:26

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User entered empty.	System	22 Dec 2020 00:13:26

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:13:26

US3702010

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:17:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User entered empty.	System	22 Dec 2020 00:13:26

US3702010

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:27

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Yes (Y)'	Jiamin Li (b) (4)	13 Oct 2020 03:02:12

US3702010

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '02 Oct 2020'	Jiamin Li (b) (4)	13 Oct 2020 03:02:12

US3702010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'No (N)'	Mia Crowley (b) (4)	02 Oct 2020 20:03:55

US3702010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User closed query 'Per CDM: Reason noted. However, No corresponding AE that caused the Investigational Product to be withdrawn is recorded in the AE CRF. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 14:40:17
User entered 'Other (OTHER)' reason for change: Data Entry Error	Jiamin Li (b) (4)	15 Jan 2021 16:12:37
Query 'Per CDM: Reason noted. However, No corresponding AE that caused the Investigational Product to be withdrawn is recorded in the AE CRF. Please review and reconcile. ' answered with 'Updated' (Site from DM).	(b) (4)	
User opened query 'Per CDM: Reason noted. However, No corresponding AE that caused the Investigational Product to be withdrawn is recorded in the AE CRF. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:09:56
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	Mia Crowley (b) (4)	02 Oct 2020 20:03:55
	(b) (4)	

US3702010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

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)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Participant refused second injection due to side effects he experienced. He consented to continue with study visits.' reason for change: Data Entry Error	Jiamin Li (b) (4)	15 Jan 2021 16:12:37
Un-reviewed for Data Management.	(b) (4), (b) (6)	30 Oct 2020 08:09:53
Reviewed for Data Management.	(b) (4), (b) (6)	30 Oct 2020 08:09:45
User entered empty.	Mia Crowley (b) (4)	02 Oct 2020 20:03:55

US3702010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User entered empty.	System	02 Oct 2020 20:03:55

US3702010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered empty.	Mia Crowley (b) (4)	02 Oct 2020 20:03:55

US3702010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered empty.	Mia Crowley (b) (4)	02 Oct 2020 20:03:55

US3702010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User entered empty.	System	02 Oct 2020 20:03:55

US3702010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered empty.	Mia Crowley (b) (4)	02 Oct 2020 20:03:55

US3702010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User entered empty.	System	02 Oct 2020 20:03:55

US3702010

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:17:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User entered empty.	System	02 Oct 2020 20:03:55

US3702010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02Oct2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however status still is the same, missing in EDC. Please review and clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 20:36:59
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02Oct2020 is reported under Visit 2 Day 29 visit 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)	23 Apr 2021 20:36:53
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02Oct2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however status still is the same, missing in EDC. Please review and clarify. Thank you. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	23 Apr 2021 18:56:47
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02Oct2020 is reported under Visit 2 Day 29 visit 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 'Updated' (Site from DM).	Jiamin Li (b) (4)	23 Apr 2021 18:56:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	23 Apr 2021 18:56:41
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02Oct2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however status still is the same, missing in EDC. Please review and clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 19:28:44

US3702010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 02Oct2020 is reported under Visit 2 Day 29 visit 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). User entered 'No (N)'	(b) (4), (b) (6) [REDACTED]	06 Jan 2021 14:29:39
	Jiamin Li (b) (4) [REDACTED]	22 Dec 2020 00:13:36

US3702010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
User entered '02 Oct 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	23 Apr 2021 18:56:41
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:13:36

US3702010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
User entered '15:24' reason for change: Data Entry Error	Jiamin Li (b) (4)	23 Apr 2021 18:56:41
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:13:36

US3702010

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User entered '02 Oct 2020 15:24'	System	23 Apr 2021 18:56:41
User entered empty.	System	22 Dec 2020 00:13:36

US3702010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:17:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 02OCT2020 is reported under Visit 2 Day 29 visit 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)	23 Apr 2021 20:37:45
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 02OCT2020 is reported under Visit 2 Day 29 visit 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 'Updated' (Site from DM).	Jiamin Li (b) (4)	23 Apr 2021 18:56:16
User entered '02 Oct 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	23 Apr 2021 18:56:03
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 02OCT2020 is reported under Visit 2 Day 29 visit 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)	02 Nov 2020 10:17:10
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 02OCT2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:17:05
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 02OCT2020 is reported under Visit 2 Day 29 visit 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)	02 Nov 2020 10:17:00

US3702010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:17:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Samples were not collected, however Collection Date is provided. Please correct.' (Site from System).	System	28 Oct 2020 15:30:52
Query 'Samples were not collected, however Collection Date is provided. Please correct.' answered by data change (Site from System).	System	28 Oct 2020 15:30:52
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	28 Oct 2020 15:30:52
User opened query 'Samples were not collected, however Collection Date is provided. Please correct.' (Site from System).	System	28 Oct 2020 15:30:43
User entered '02 Oct 2020'	Jiamin Li (b) (4)	28 Oct 2020 15:30:43

US3702010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:17:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jiamin Li (b) (4) (b) (4)	28 Oct 2020 15:30:43

US3702010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:17:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	23 Apr 2021 18:56:03
User entered 'No (N)'	Jiamin Li (b) (4)	28 Oct 2020 15:30:43

US3702010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:17:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
User entered '15:35' reason for change: Data Entry Error	Jiamin Li (b) (4)	23 Apr 2021 18:56:03
User entered empty.	Jiamin Li (b) (4)	28 Oct 2020 15:30:43

US3702010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:17:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User entered '02 Oct 2020 15:35'	System	23 Apr 2021 18:56:03
User entered empty.	System	28 Oct 2020 15:30:43

US3702010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:17:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jiamin Li (b) (4) (b) (4)	28 Oct 2020 15:30:43

US3702010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:17:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
User entered 'No (N)'	Jiamin Li (b) (4)	28 Oct 2020 15:30:43

US3702010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:17:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
User entered empty.	Jiamin Li (b) (4)	28 Oct 2020 15:30:43

US3702010

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:17:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User entered empty.	System	28 Oct 2020 15:30:43

US3702010

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Yes (Y)'	Jiamin Li (b) (4)	13 Oct 2020 03:02:49

US3702010

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:41:54
User entered '1'	System	13 Oct 2020 03:02:49

US3702010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:17
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Genessi Rodriguez (b) (4)	19 Oct 2020 15:36:10

US3702010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:17
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '9 Oct 2020'	Genessi Rodriguez (b) (4)	19 Oct 2020 15:36:10

US3702010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:17
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Contact Not Made (CONTACT NOT MADE)'	Genessi Rodriguez (b) (4)	19 Oct 2020 15:36:10

US3702010

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:17
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	19 Oct 2020 15:41:10
User entered 'Patient was unable to reach' reason for change: Data Entry Error	Genessi Rodriguez (b) (4)	19 Oct 2020 15:41:10
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	19 Oct 2020 15:36:10
User entered empty.	Genessi Rodriguez (b) (4)	19 Oct 2020 15:36:10

US3702010

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:17
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	27 Oct 2020 02:05:21

US3702010

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:16:17
User entered '1'	System	27 Oct 2020 02:05:21

US3702010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:13:10
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	27 Oct 2020 02:09:03
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	27 Oct 2020 02:08:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	27 Oct 2020 02:08:54
User entered 'No (N)'	Jiamin Li (b) (4)	27 Oct 2020 02:06:26

US3702010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:13:10
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '19 Oct 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	27 Oct 2020 02:08:54
User entered empty.	Jiamin Li (b) (4)	27 Oct 2020 02:06:26

US3702010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:13:10
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Jiamin Li (b) (4)	27 Oct 2020 02:09:03
User entered empty.	Jiamin Li (b) (4)	27 Oct 2020 02:06:26

US3702010

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:13:10
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	27 Oct 2020 02:06:26

US3702010

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:13:10
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	27 Oct 2020 02:06:31

US3702010

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:13:10
User entered '1'	System	27 Oct 2020 02:06:31

US3702010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:08:35
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	27 Oct 2020 02:06:41

US3702010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:08:35
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30-OCT-2020 is reported under Visit 3 Day 57 in PPD portal; however, immunogenicity sample is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 18:01:49
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30-OCT-2020 is reported under Visit 3 Day 57 in PPD portal; however, immunogenicity sample is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	22 Dec 2020 00:06:27
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30-OCT-2020 is reported under Visit 3 Day 57 in PPD portal; however, immunogenicity sample is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 10:35:45
User entered '26 Oct 2020'	Jiamin Li (b) (4)	27 Oct 2020 02:06:41

US3702010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:08:35
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	27 Oct 2020 02:06:41

US3702010

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:08:35
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	27 Oct 2020 02:06:41

US3702010

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:08:35
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	27 Oct 2020 02:07:38

US3702010

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:08:35
User entered '1'	System	27 Oct 2020 02:07:38

US3702010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Dec 2020 00:14:44

US3702010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '30 Oct 2020'	Jiamin Li (b) (4)	22 Dec 2020 00:14:44

US3702010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Clinic (Clinic)'	Jiamin Li (b) (4)	22 Dec 2020 00:14:44

US3702010

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User entered 'VISIT3'	System	22 Dec 2020 00:14:44

US3702010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Dec 2020 00:16:48

US3702010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '30 Oct 2020'	Jiamin Li (b) (4)	22 Dec 2020 00:16:48

US3702010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Dec 2020 16:25:15
Query 'Data is required. Please provide.' answered with 'Information not evaluated.' (Site from System).	Jiamin Li (b) (4)	22 Dec 2020 00:16:55
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Dec 2020 00:16:48
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:16:48

US3702010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User entered empty.	System	22 Dec 2020 00:16:48

US3702010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '98.2' F	Jiamin Li (b) (4)	22 Dec 2020 00:16:48

US3702010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Other (Other)'	Jiamin Li (b) (4)	22 Dec 2020 00:16:48

US3702010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Information not specified.'	Jiamin Li (b) (4)	22 Dec 2020 00:16:48

US3702010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '62'	Jiamin Li (b) (4)	22 Dec 2020 00:16:48

US3702010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User entered 'bpm'	System	22 Dec 2020 00:16:48

US3702010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Dec 2020 16:25:04
Query 'Data is required. Please provide.' answered with 'Information not evaluated.' (Site from System).	Jiamin Li (b) (4)	22 Dec 2020 00:16:58
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Dec 2020 00:16:48
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:16:48

US3702010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User entered empty.	System	22 Dec 2020 00:16:48

US3702010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '153'	Jiamin Li (b) (4)	22 Dec 2020 00:16:48

US3702010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User entered 'mmHg'	System	22 Dec 2020 00:16:48

US3702010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '75'	Jiamin Li (b) (4)	22 Dec 2020 00:16:48

US3702010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User entered 'mmHg'	System	22 Dec 2020 00:16:48

US3702010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02

US3702010

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02

US3702010

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:27

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Dec 2020 00:15:37

US3702010

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '30 Oct 2020'	Jiamin Li (b) (4)	22 Dec 2020 00:15:37

US3702010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	22 Dec 2020 00:17:23
User entered 'No (N)'	Jiamin Li (b) (4)	22 Dec 2020 00:17:05

US3702010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '30 Oct 2020' reason for change: Data Entry Error	Jiamin Li (b) (4)	22 Dec 2020 00:17:23
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:17:05

US3702010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered '15:54' reason for change: Data Entry Error	Jiamin Li (b) (4)	22 Dec 2020 00:17:23
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:17:05

US3702010

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:17:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User entered '30 Oct 2020 15:54'	System	22 Dec 2020 00:17:23
User entered empty.	System	22 Dec 2020 00:17:05

US3702010

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:14:23
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Dec 2020 00:15:44

US3702010

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:02
User entered '1'	System	22 Dec 2020 00:15:44

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 64'	System	04 Sep 2020 18:51:29

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13
Data entry locked.	System	04 Sep 2020 18:51:29
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 18:51:29

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13
Data entry locked.	System	04 Sep 2020 18:51:29
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 71'	System	04 Sep 2020 18:51:29

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13
Data entry locked.	System	04 Sep 2020 18:51:29
User entered '11 Nov 2020 00:01'	System	04 Sep 2020 18:51:29

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13
Data entry locked.	System	04 Sep 2020 18:51:29
User entered '15 Nov 2020 23:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13
Data entry locked.	System	04 Sep 2020 18:51:29
User entered 'Day 78'	System	04 Sep 2020 18:51:29

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

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)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13

US3702010

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13
Data entry locked.	System	04 Sep 2020 18:51:29
User entered '18 Nov 2020 00:01'	System	04 Sep 2020 18:51:29

US3702010

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)	02 May 2021 14:25:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:05:13
Data entry locked.	System	04 Sep 2020 18:51:29
User entered '22 Nov 2020 23:59'	System	04 Sep 2020 18:51:29

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New 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)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
	[REDACTED]	
	[REDACTED]	

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 04:05:13

US3702010

Folder: New 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)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
	[Redacted]	
	[Redacted]	

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
	[REDACTED]	
	[REDACTED]	

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
	[REDACTED]	
	[REDACTED]	

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
	[REDACTED]	
	[REDACTED]	

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
	[REDACTED]	
	[REDACTED]	

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 04:05:13

US3702010

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:17:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:05:13
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 04:05:13

US3702010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:58:35
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Dec 2020 00:18:10

US3702010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:58:35
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '25 Nov 2020'	Jiamin Li (b) (4)	22 Dec 2020 00:18:10

US3702010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:58:35
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	22 Dec 2020 00:18:10

US3702010

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:58:35
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:18:10

US3702010

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:58:35
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Dec 2020 00:18:16

US3702010

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:58:35
User entered 'I'	System	22 Dec 2020 00:18:16

US3702010

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:52:24
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Jan 2021 02:34:58

US3702010

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:52:24
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '31 Dec 2020'	Jiamin Li (b) (4)	12 Jan 2021 02:34:58

US3702010

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:52:24
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Contact Made (CONTACT MADE)'	Jiamin Li (b) (4)	12 Jan 2021 02:34:58

US3702010

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:52:24
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:34:58

US3702010

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:52:24
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Jan 2021 02:35:02

US3702010

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:52:24
User entered '1'	System	12 Jan 2021 02:35:02

US3702010

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	01 Feb 2021 10:15:54

US3702010

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	01 Feb 2021 10:15:54

US3702010

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	01 Feb 2021 10:15:54

US3702010

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	01 Feb 2021 10:15:54

US3702010

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	01 Feb 2021 10:16:00

US3702010

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered 'I'	System	01 Feb 2021 10:16:00

US3702010

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	09 Apr 2021 19:20:40
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Mar 2021 14:13:18

US3702010

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
User closed query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	09 Apr 2021 19:20:40
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	09 Apr 2021 19:20:40
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	09 Apr 2021 19:20:40
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	12 Mar 2021 17:46:04
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	12 Mar 2021 17:46:04
User entered '01 Mar 2021'	Jiamin Li (b) (4)	02 Mar 2021 14:13:18

US3702010

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	09 Apr 2021 19:20:40
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jiamin Li (b) (4)	02 Mar 2021 14:13:18

US3702010

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:17:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	09 Apr 2021 19:20:40
User entered 'Participant remains hospitalized'	Jiamin Li (b) (4)	02 Mar 2021 14:13:18

US3702010

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	02 Mar 2021 14:13:24

US3702010

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:17:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered 'I'	System	02 Mar 2021 14:13:24

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:17:27

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:32:51
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 18:32:48
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:10:15
User entered '05 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	27 Jan 2021 21:19:36
User entered '05 Jan 2020'	Jiamin Li (b) (4)	12 Jan 2021 02:39:43

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:17:27

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:32:51
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 18:32:48
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:10:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Feb 2021 13:13:58
Query 'Data is required. Please complete.' answered with 'Information not assessed' (Site from System).	Jiamin Li (b) (4)	12 Jan 2021 02:39:49
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Jan 2021 02:39:43
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:39:43

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:17:27

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:32:51
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 18:32:48
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered empty.	System	12 Jan 2021 02:39:43

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:17:27

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:32:51
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 18:32:48
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:10:15
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Jiamin Li (b) (4)	12 Jan 2021 02:39:43

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:17:27

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:32:51
Data hard unlocked.	(b) (4), (b) (6)	03 May 2021 18:32:48
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:10:15
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Jan 2021 02:39:43
	(b) (4)	

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Feb 2021 10:14:15
User entered 'Day 1 (Day 1)'	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User closed query 'Per ETRTR: COVID-19 AE Start date is 01Jan21. Please add log lines since 01Jan21 through 04Jan21 as expected per onset of Symptoms reported, thanks.' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 15:24:37
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:13:52
Query 'Per ETRTR: COVID-19 AE Start date is 01Jan21. Please add log lines since 01Jan21 through 04Jan21 as expected per onset of Symptoms reported, thanks.' answered with 'Updated' (Site from CRA).	Jiamin Li (b) (4)	01 Feb 2021 10:14:24
User opened query 'Per ETRTR: COVID-19 AE Start date is 01Jan21. Please add log lines since 01Jan21 through 04Jan21 as expected per onset of Symptoms reported, thanks.' (Site from CRA).	(b) (4), (b) (6)	29 Jan 2021 19:04:48
User entered '05 Jan 2021'	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:37:19
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'l'	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:37:20
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User closed query 'O2 Saturation for 5Jan2021 available in patient source. Please review and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 19:11:07
Query 'O2 Saturation for 5Jan2021 available in patient source. Please review and update accordingly.' answered with 'Updated' (Site from CRA).	Jiamin Li (b) (4)	16 Feb 2021 18:19:01
User entered '90' reason for change: Data Entry Error	Jiamin Li (b) (4)	16 Feb 2021 18:18:57
User opened query 'O2 Saturation for 5Jan2021 available in patient source. Please review and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:16:17
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '%'	System	16 Feb 2021 18:18:57
User entered empty.	System	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:37:42
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '38.3' C reason for change: Data Entry Error	Jiamin Li (b) (4)	16 Feb 2021 18:18:57
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:16:25
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:16:48
User entered 'Moderate (Moderate)'	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:16:51
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User closed query 'Documented in source as severe. Please review and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 19:11:21
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:11:19
Query 'Documented in source as severe. Please review and update accordingly.' answered with 'Updated' (Site from CRA).	Jiamin Li (b) (4)	16 Feb 2021 18:18:49
User entered 'Severe (Severe)' reason for change: Data Entry Error	Jiamin Li (b) (4)	16 Feb 2021 18:18:44
User opened query 'Documented in source as severe. Please review and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:17:34
User entered 'Moderate (Moderate)'	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:17:46
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:17:54
User entered 'None (None)'	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:17:58
User entered 'None (None)'	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:17:56
User entered 'None (None)'	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:18:05
User entered 'None (None)'	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:18:08
User entered 'None (None)'	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:18:11
User entered 'Severe (Severe)'	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:18:14
User entered 'None (None)'	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:18:31
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:18:36
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:18:35
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:17:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:18:39
User entered 'None (None)'	Jiamin Li (b) (4)	12 Jan 2021 02:40:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Feb 2021 10:14:15
User entered 'Day 8 (Day 8)'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:19:15
User entered '12 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:38:18
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:20:15
User entered '94'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '%'	System	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:20:40
User entered '36.9' C	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:20:44
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:20:55
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:20:59
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:21:07
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:21:10
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:21:14
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:21:21
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:21:22
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:21:36
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:21:42
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:21:48
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:21:51
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:21:53
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:21:54
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:21:58
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:17:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:22:00
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:23:29

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Feb 2021 10:14:15
User entered 'Day 2 (Day 2)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:22:28
User entered '06 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:22:31
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:11:48
User closed query 'O2 Saturation documented in source for 5-6Jan2021 as 96; please review and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 19:11:46
Query 'O2 Saturation documented in source for 5-6Jan2021 as 96; please review and update accordingly.' answered with 'Updated' (Site from CRA).	Jiamin Li (b) (4)	16 Feb 2021 18:20:16
User entered '96' reason for change: Data Entry Error	Jiamin Li (b) (4)	16 Feb 2021 18:20:11
User opened query 'O2 Saturation documented in source for 5-6Jan2021 as 96; please review and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:23:21
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '%'	System	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:22:22
User entered '36.8' C	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:23:32
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:23:36
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:23:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:23:52
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:23:55
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:24:14
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:24:13
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:24:11
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:24:09
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:24:07
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:24:23
User entered 'Moderate (Moderate)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:24:31
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:24:32
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:24:34
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:24:35
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:17:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:24:37
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:04

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Feb 2021 10:14:15
User entered 'Day 3 (Day 3)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:26:33
User entered '07 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:26:34
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:26:36
User entered '96'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '%'	System	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:26:39
User entered '36.8' C	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:26:43
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:26:53
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:26:58
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:27:01
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:27:04
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:27:14
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:27:16
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:27:34
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:27:32
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:27:31
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:27:49
User entered 'Moderate (Moderate)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:27:56
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:28:06
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:28:03
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:28:00
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:17:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:27:58
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:25:59

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Feb 2021 10:14:15
User entered 'Day 4 (Day 4)'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:28:45
User entered '08 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:28:49
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:28:52
User entered '94'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '%'	System	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:28:54
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:29:02
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:29:10
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:29:25
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:29:27
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:29:31
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:29:43
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:29:41
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:29:39
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:29:37
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:29:35
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:29:53
User entered 'Moderate (Moderate)'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:30:00
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:30:03
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:30:05
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:30:06
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:17:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:30:08
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:28:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Feb 2021 10:14:15
User entered 'Day 5 (Day 5)'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:30:32
User entered '09 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:30:40
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:30:38
User entered '94'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '%'	System	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:30:37
User entered '37.1' C	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:30:55
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:31:01
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:31:09
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:31:07
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:31:06
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:31:26
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:31:23
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:31:21
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:31:19
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:31:16
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:31:47
User entered 'Moderate (Moderate)'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:32:02
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:32:00
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:31:58
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:31:56
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:17:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:31:54
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:29:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Feb 2021 10:14:15
User entered 'Day 6 (Day 6)'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:32:18
User entered '10 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:32:20
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:32:25
User entered '94'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '%'	System	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:32:37
User entered '37.3' C	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:32:47
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:32:50
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:33:07
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:33:05
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:33:04
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:33:22
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:33:19
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:33:17
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:33:15
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:33:13
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:33:30
User entered 'Moderate (Moderate)'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:33:47
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:33:44
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:33:40
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:33:38
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:17:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:33:36
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:30:41

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Feb 2021 10:14:15
User entered 'Day 7 (Day 7)'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:34:09
User entered '11 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:34:11
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:34:12
User entered '93'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '%'	System	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:34:17
User entered '36.8' C	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:34:26
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:34:29
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:34:37
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:34:40
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:34:44
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:34:52
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:34:50
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:35:05
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:35:04
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:35:02
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	22 Feb 2021 19:12:13
User closed query 'Documented in subject source for 11Jan2021 as moderate; please review and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 19:12:11
Query 'Documented in subject source for 11Jan2021 as moderate; please review and update accordingly.' answered with 'Updated' (Site from CRA).	Jiamin Li (b) (4)	16 Feb 2021 18:20:50
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Jiamin Li (b) (4)	16 Feb 2021 18:20:46
User opened query 'Documented in subject source for 11Jan2021 as moderate; please review and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:36:01
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:36:19
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:36:15
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:36:12
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:36:11
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:17:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:36:09
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:31:36

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Feb 2021 10:14:15
User entered 'Day 9 (Day 9)'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:37:14
User entered '13 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:37:15
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:37:24
User entered '94'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '%'	System	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:37:19
User entered '98.1' F	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:37:52
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:37:50
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:37:58
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:37:56
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:38:09
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:38:11
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:38:12
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:38:14
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:38:16
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:38:18
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:38:20
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:38:25
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:38:27
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:38:30
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:38:32
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:17:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:38:34
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:36:54

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Feb 2021 10:14:15
User entered 'Day 10 (Day 10)'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:19
User entered '14 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:17
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:16
User entered '94'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '%'	System	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:14
User entered '97.7' F	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:32
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:30
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:37
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:46
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:49
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:52
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:54
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:56
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:42:58
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:02
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:04
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:06
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:09
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:11
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:14
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:17:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:16
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:39:46

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Feb 2021 10:14:15
User entered 'Day 11 (Day 11)'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:29
User entered '15 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:41
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:37
User entered '94'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '%'	System	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:36
User entered '98.1' F	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:45
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:49
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:53
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:44:11
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:44:09
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:44:07
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:44:04
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:44:03
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:44:01
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:43:59
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:44:15
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:44:17
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:44:20
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:44:23
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:44:25
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:17:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:44:29
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:40:22

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Feb 2021 10:14:15
User entered 'Day 12 (Day 12)'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:45:26
User entered '16 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 17:11:26
User entered '19 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:45:23
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:45:21
User entered '96'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '%'	System	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:45:15
User entered '97.5' F	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:45:31
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:45:40
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:45:43
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:45:48
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:46:06
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:46:04
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:46:01
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:45:59
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:45:57
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:45:55
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:46:19
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:46:32
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:46:30
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:46:27
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:46:25
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:17:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:46:23
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 15:43:18

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Day 17 (Day 17)' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Feb 2021 10:14:15
User entered 'Day 13 (Day 13)'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:46:51
User entered '17 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:46:46
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:46:43
User entered '93'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '%'	System	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:46:41
User entered '98.1' F	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:47:00
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:47:02
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:47:04
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:47:07
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:47:34
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:47:32
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:47:29
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:47:27
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:47:25
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:47:22
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:47:49
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:48:12
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:48:18
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:48:04
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:48:00
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:17:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:47:56
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:12:38

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Day 18 (Day 18)' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Feb 2021 10:14:15
User entered 'Day 14 (Day 14)'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:48:42
User entered '18 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:48:40
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:48:34
User entered '97'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '%'	System	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:48:38
User entered '100.8' F	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:48:51
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:48:52
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:48:58
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:48:59
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:49:16
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:49:14
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:49:13
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:49:11
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:49:09
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:49:08
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:49:26
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:49:32
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:49:40
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:49:39
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:49:37
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (14)

Generated On: 10 Jun 2021 09:17:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:49:35
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:14:15

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Day 19 (Day 19)' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Feb 2021 10:14:15
User entered 'Day 15 (Day 15)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:50:00
User entered '19 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:50:02
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:50:04
User entered '94'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '%'	System	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:50:06
User entered '100.1' F	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:50:13
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:50:14
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:50:25
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:50:32
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:50:44
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:50:42
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:50:40
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:50:39
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:50:37
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:50:36
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:50:55
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:50:59
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:51:08
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:51:06
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:51:04
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (15)

Generated On: 10 Jun 2021 09:17:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:51:02
User entered 'None (None)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:00

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Day 1 (Day 1)'	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:51:40
User entered '01 Jan 2021'	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:51:42
User entered '0'	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:32:39
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '%'	System	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:32:41
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:32:52
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:32:56
User entered 'Moderate (Moderate)'	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:33:03
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:33:18
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:33:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	Jiamin Li (b) (4)	01 Feb 2021 10:10:41
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:33:41
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:33:39
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:33:37
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:33:35
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:33:34
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:34:23
User entered 'Severe (Severe)'	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:34:25
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:34:01
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:34:03
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:33:55
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (16)

Generated On: 10 Jun 2021 09:17:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:34:05
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:09:17

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Day 2 (Day 2)'	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:34:34
User entered '02 Jan 2021'	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:34:35
User entered '0'	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:34:39
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '%'	System	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:34:37
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:34:51
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:34:55
User entered 'Moderate (Moderate)'	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:34:56
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:35:02
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:35:08
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:35:15
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:35:13
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:35:12
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:35:28
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:35:27
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:35:50
User entered 'Severe (Severe)'	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:36:07
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:36:05
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:36:03
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:36:01
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (17)

Generated On: 10 Jun 2021 09:17:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:36:00
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:10:20

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Day 3 (Day 3)'	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:36:25
User entered '03 Jan 2021'	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:36:24
User entered '0'	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:36:21
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '%'	System	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 21:36:19
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:19:52
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:19:58
User entered 'Moderate (Moderate)'	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:20:08
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:20:13
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:20:17
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:20:42
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:20:40
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:20:38
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:20:36
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:20:33
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:20:28
User entered 'Severe (Severe)'	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:21:01
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:21:00
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:20:57
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:20:55
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (18)

Generated On: 10 Jun 2021 09:17:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:20:53
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:11:42

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Day 4 (Day 4)'	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:21:17
User entered '04 Jan 2021'	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:21:22
User entered '0'	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:21:23
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '%'	System	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:21:25
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:21:32
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:21:35
User entered 'Moderate (Moderate)'	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:21:39
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:21:43
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:21:46
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:21:58
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:22:00
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:22:02
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:22:05
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:21:56
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:22:33
User entered 'Severe (Severe)'	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:22:35
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:22:38
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:22:42
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:22:48
User entered 'Mild (Mild)'	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Symptom Log (19)

Generated On: 10 Jun 2021 09:17:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:22:45
User entered 'None (None)'	Jiamin Li (b) (4)	01 Feb 2021 10:12:34

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:17:27

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:26:00
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: PPD has a sample date 08JAN2020 under Illness Visit Day1 which is missing in EDC. In EDC, COVID swab dated 05Jan2021 is recorded. Please review Preclarus to verify the Year reported and update Preclarus, as appropriate. Also kindly confirm the correct date in the response and record the data in EDC.	(b) (4), (b) (6)	29 Jan 2021 06:40:12
' (Site from DM). Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: PPD has a sample date 08JAN2020 under Illness Visit Day1 which is missing in EDC. In EDC, COVID swab dated 05Jan2021 is recorded. Please review Preclarus to verify the Year reported and update Preclarus, as appropriate. Also kindly confirm the correct date in the response and record the data in EDC.	Jiamin Li (b) (4)	26 Jan 2021 15:35:01
' answered with 'Updated' (Site from DM). User entered '08 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 15:34:58
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: PPD has a sample date 08JAN2020 under Illness Visit Day1 which is missing in EDC. In EDC, COVID swab dated 05Jan2021 is recorded. Please review Preclarus to verify the Year reported and update Preclarus, as appropriate. Also kindly confirm the correct date in the response and record the data in EDC.	(b) (4), (b) (6)	13 Jan 2021 08:07:00
' (Site from DM). User entered '05 Jan 2021'	Jiamin Li (b) (4)	12 Jan 2021 02:43:27

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:17:27

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:26:09
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Jan 2021 02:43:27

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:17:27

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:26:11
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 21:17:25
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'Updated' (Site from System).	Jiamin Li (b) (4)	12 Jan 2021 02:44:35
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Jan 2021 02:44:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Jan 2021 02:44:27
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	12 Jan 2021 02:44:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Jan 2021 02:44:27
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Jan 2021 02:43:27
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:43:27

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:17:27

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
User closed query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 18:28:03
Query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' answered with 'A covid-19 illness visit already existss' (Site from DM).	Jiamin Li (b) (4)	09 Apr 2021 19:09:17
User opened query 'Per CDM: A diagnostic test has been completed; however, the associated Illness visit has not been added to the database. Please agree to add a COVID-19 Illness Visit via Add Events and complete all Illness visit forms, or else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 18:43:51
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:26:18
User entered '08 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 15:34:58
User entered '05 Jan 2021'	Jiamin Li (b) (4)	12 Jan 2021 02:43:27

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:17:27

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:26:26
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Jiamin Li (b) (4)	12 Jan 2021 02:43:27

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:17:27

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:26:30
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:43:27

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:17:27

[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)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:26:46
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:43:27

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:17:27

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:26:50
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:43:27

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:17:27

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:26:55
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:43:27

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:17:27

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '1'	System	12 Jan 2021 02:44:27

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:56:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
DataPoint Un-verified.	Jiamin Li (b) (4)	12 Mar 2021 17:25:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 17:25:48
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:27:21
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:28:25
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:28:23
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:28:22
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:35:08
User closed query 'Per sponsor review: did the subject have Heart Rate \geq 125 beats per minute is marked YES but start and end date are missing, please review and reconcile or otherwise clarify' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 18:30:02
Query 'Per sponsor review: did the subject have Heart Rate \geq 125 beats per minute is marked YES but start and end date are missing, please review and reconcile or otherwise clarify' answered with 'Information pending - patient passed away in an external hospital system and we are still trying to obtain medical records and further information.' (Site from DM).	Jiamin Li (b) (4)	09 Apr 2021 19:10:28
User opened query 'Per sponsor review: did the subject have Heart Rate \geq 125 beats per minute is marked YES but start and end date are missing, please review and reconcile or otherwise clarify' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 22:28:24
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Un-verified.	Jiamin Li (b) (4)	12 Mar 2021 17:25:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 17:25:48
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:28:20
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:28:17
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:28:14
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:28:12
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

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)	02 May 2021 17:35:50
User closed query 'Per sponsor review: Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? Is marked YES but end date is missing, please review and reconcile or otherwise clarify' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 18:30:00
Query 'Per sponsor review: Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? Is marked YES but end date is missing, please review and reconcile or otherwise clarify' answered with 'Information pending - patient passed away in an external hospital system and we are still trying to obtain medical records and further information.' (Site from DM).	Jiamin Li (b) (4)	09 Apr 2021 19:10:51
User opened query 'Per sponsor review: Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level? Is marked YES but end date is missing, please review and reconcile or otherwise clarify' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 22:29:02
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:28:09
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:39:52
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Un-verified.	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
User entered '05 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:28:05
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:28:03
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 23:01:44
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Un-verified.	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
User entered '90' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:28:02
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:39:53
User closed query 'Per sponsor review: Did the subject have PaO2/FIO2 Ratio < 300 mm Hg? Is marked Yes but start and end date are missing, please review and reconcile or otherwise clarify' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 18:29:58
Query 'Per sponsor review: Did the subject have PaO2/FIO2 Ratio < 300 mm Hg? Is marked Yes but start and end date are missing, please review and reconcile or otherwise clarify' answered with 'Information pending - patient passed away in an external hospital system and we are still trying to obtain medical records and further information.' (Site from DM).	Jiamin Li (b) (4) (b) (4)	09 Apr 2021 19:11:09
User opened query 'Per sponsor review: Did the subject have PaO2/FIO2 Ratio < 300 mm Hg? Is marked Yes but start and end date are missing, please review and reconcile or otherwise clarify' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 22:29:43
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Un-verified.	Jiamin Li (b) (4) (b) (4)	12 Mar 2021 20:02:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	12 Mar 2021 20:02:32
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:28:00
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:27:57
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:27:55
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:27:54
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:51:32
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Un-verified.	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:27:50
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:51:33
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Un-verified.	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
User entered '24 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:27:48
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:51:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Un-verified.	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:27:47
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:51:57
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Un-verified.	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
User entered '20 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:27:44
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:32:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	05 Feb 2021 03:27:02
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:32:31
User entered '20 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	05 Feb 2021 03:27:02
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:51:23
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Un-verified.	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
User entered '24 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:32:33
User entered '23 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	05 Feb 2021 03:27:02
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:51:18
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Un-verified.	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:32:37
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:51:12
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Un-verified.	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
User entered '21 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:32:54
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:51:20
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Un-verified.	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
User entered '24 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:32:53
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:32:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	05 Feb 2021 03:27:02
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:50:10
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Un-verified.	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
User entered '24 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:32:51
User entered '23 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	05 Feb 2021 03:27:02
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:50:48
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Un-verified.	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
User entered '25 Feb 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:35:06
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:35:07
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:35:09
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:35:15
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:46:51
User closed query 'Per sponsor review: Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg is marked YES but start and end date are missing, please review and reconcile or otherwise clarify' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 18:30:07
Query 'Per sponsor review: Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg is marked YES but start and end date are missing, please review and reconcile or otherwise clarify' answered with 'Information pending - patient passed away in an external hospital system and we are still trying to obtain medical records and further information.' (Site from DM).	Jiamin Li (b) (4) (b) (4)	09 Apr 2021 19:11:25
User opened query 'Per sponsor review: Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg is marked YES but start and end date are missing, please review and reconcile or otherwise clarify' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 22:30:20
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Un-verified.	Jiamin Li (b) (4) (b) (4)	12 Mar 2021 20:02:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	12 Mar 2021 20:02:32
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:35:32
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:35:34
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:35:36
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User closed query 'Per sponsor review: Evidence of Shock Requires Vasopressors is marked YES but start and end date are missing, please review and reconcile or otherwise clarify' ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 18:30:08
Query 'Per sponsor review: Evidence of Shock Requires Vasopressors is marked YES but start and end date are missing, please review and reconcile or otherwise clarify' ' answered with 'Information pending - patient passed away in an external hospital system and we are still trying to obtain medical records and further information.' (Site from DM).	Jiamin Li (b) (4) (b) (4)	09 Apr 2021 19:11:46
User opened query 'Per sponsor review: Evidence of Shock Requires Vasopressors is marked YES but start and end date are missing, please review and reconcile or otherwise clarify' ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 22:30:47
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:35:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	05 Feb 2021 03:27:02
User entered 'No (N)'	Jiamin Li (b) (4) (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:46:42
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Un-verified.	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 20:02:32
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:35:40
User entered '23 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	05 Feb 2021 03:27:02
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:35:42
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:35:44
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:35:46
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:35:53
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:35:55
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:35:56
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:36:03
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:36:40
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:36:42
User entered '05 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	05 Feb 2021 03:27:02
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:36:44
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:36:46
User entered '05 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	05 Feb 2021 03:27:02
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:36:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	05 Feb 2021 03:27:02
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:50:56
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Un-verified.	Jiamin Li (b) (4)	12 Mar 2021 17:25:48
User entered '24 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 17:25:48
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:36:51
User entered '23 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	05 Feb 2021 03:27:02
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 10 Jun 2021 09:17:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 17:50:57
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Un-verified.	Jiamin Li (b) (4)	12 Mar 2021 17:25:48
User entered '25 Feb 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 17:25:48
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:36:53
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:21

US3702010

Folder: Covid-19 Assessment 05 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:17:27

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:31:36
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:43:35

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:17:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User accepted default value 'Day 3 (Day 3)'	Jiamin Li (b) (4) (b) (4)	26 Jan 2021 15:33:36

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:17:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:03:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 15:37:47
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:33:36

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:17:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Sample mislabeled in PPD as US3652010. A note to file will be uploaded for the monitor and the lab personnel has called PPD for correction. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 06:03:02
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	Jiamin Li (b) (4)	23 Apr 2021 16:27:00
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking 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)	09 Feb 2021 06:03:07
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:03:49
User entered '11 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 15:37:47
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:33:36

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:17:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User accepted default value 'Day 5 (Day 5)'	Jiamin Li (b) (4)	26 Jan 2021 15:33:42

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:17:27

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 19:58:39
DataPoint Un-verified.	Jiamin Li (b) (4)	23 Apr 2021 16:32:57
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	23 Apr 2021 16:32:57
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:04:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 15:37:55
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:33:42

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:17:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 19:58:39
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Sample not collected' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 06:03:59
DataPoint Un-verified.	Jiamin Li (b) (4)	23 Apr 2021 16:33:12
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	23 Apr 2021 16:32:57
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking 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)	09 Feb 2021 06:03:24
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:04:03
User entered '13 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 15:37:55
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:33:42

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:17:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User accepted default value 'Day 7 (Day 7)'	Jiamin Li (b) (4)	26 Jan 2021 15:33:53

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:17:27

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 19:58:39
DataPoint Un-verified.	Jiamin Li (b) (4)	23 Apr 2021 16:34:34
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	23 Apr 2021 16:34:34
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:04:17
User entered 'Yes (Y)'	Jiamin Li (b) (4)	26 Jan 2021 15:33:53

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:17:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 19:58:39
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Sample not collected' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 06:04:03
DataPoint Un-verified.	Jiamin Li (b) (4)	23 Apr 2021 16:34:50
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	23 Apr 2021 16:34:34
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking 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)	15 Feb 2021 04:04:15

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:17:27

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 04:03:58
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16JAN2021 is recorded under Illness visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number, Shipping date and tracking 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)	09 Feb 2021 06:04:30
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:04:18
User entered '15 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 15:38:05
User entered '11 Jan 2021'	(b) (4)	
	Jiamin Li (b) (4)	26 Jan 2021 15:33:53
	(b) (4)	

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:17:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User accepted default value 'Day 9 (Day 9)'	Jiamin Li (b) (4) (b) (4)	27 Jan 2021 21:18:11

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:17:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:05:39
User entered 'No (N)'	Jiamin Li (b) (4)	27 Jan 2021 21:18:11

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:17:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:05:41
User entered empty.	Jiamin Li (b) (4)	27 Jan 2021 21:18:11

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:17:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User accepted default value 'Day 14 (Day 14)'	Jiamin Li (b) (4)	27 Jan 2021 21:18:18

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:17:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:05:35
User entered 'No (N)'	Jiamin Li (b) (4)	27 Jan 2021 21:18:18

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:17:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:05:36
User entered empty.	Jiamin Li (b) (4)	27 Jan 2021 21:18:18

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:17:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User accepted default value 'Day 21 (Day 21)'	Jiamin Li (b) (4)	17 Mar 2021 19:17:07

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:17:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:56:16
User entered 'No (N)'	Jiamin Li (b) (4)	17 Mar 2021 19:17:07

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:17:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:56:16
User entered empty.	Jiamin Li (b) (4)	17 Mar 2021 19:17:07

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:17:27

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User accepted default value 'Day 28 (Day 28)'	Jiamin Li (b) (4)	17 Mar 2021 19:17:07

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:17:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:56:16
User entered 'No (N)'	Jiamin Li (b) (4)	17 Mar 2021 19:17:07

US3702010

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:17:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:56:16
User entered empty.	Jiamin Li (b) (4)	17 Mar 2021 19:17:07

US3702010

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:36:57
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:37:58
User closed query 'Per ETRTR: Please complete data entry within Vital Signs page, thanks.' (Site from CRA).	(b) (4), (b) (6)	04 Feb 2021 16:58:48
Query 'Per ETRTR: Please complete data entry within Vital Signs page, thanks.' answered with 'Updated' (Site from CRA).	Jiamin Li (b) (4)	01 Feb 2021 09:59:24
User opened query 'Per ETRTR: Please complete data entry within Vital Signs page, thanks.' (Site from CRA).	(b) (4), (b) (6)	29 Jan 2021 19:02:57
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Jan 2021 02:42:09

US3702010

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:36:57
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:37:59
User entered '05 Jan 2021'	Jiamin Li (b) (4)	12 Jan 2021 02:42:09

US3702010

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

[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 02:36:57
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:38:01
User entered 'Clinic (Clinic)'	Jiamin Li (b) (4)	12 Jan 2021 02:42:09

US3702010

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:36:57
User entered 'SICKD1'	System	12 Jan 2021 02:42:09

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:08
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:39:36
User closed query 'Per CDM: Were vitals signs assessed is blank. Please update yes or no.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 15:06:06
User entered 'Yes (Y)'	Jiamin Li (b) (4)	01 Feb 2021 10:00:02
Query 'Per CDM: Were vitals signs assessed is blank. Please update yes or no.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	01 Feb 2021 09:59:31
User opened query 'Per CDM: Were vitals signs assessed is blank. Please update yes or no.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 14:00:56

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:08
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:39:36
User entered '05 Jan 2021'	Jiamin Li (b) (4)	01 Feb 2021 10:00:02

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:08
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:39:36
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	02 Feb 2021 14:43:50
Query 'Data is required. Please provide.' answered with 'Information not captured.' (Site from System).	Jiamin Li (b) (4)	01 Feb 2021 10:00:09
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Feb 2021 10:00:02
User entered empty.	System	01 Feb 2021 10:00:02
	Jiamin Li (b) (4)	01 Feb 2021 10:00:02
	(b) (4)	

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:08
User entered empty.	System	01 Feb 2021 10:00:02

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:08
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:39:36
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	01 Feb 2021 10:00:02
DataPoint set to visible.	(b) (4) System	12 Jan 2021 02:42:09

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:08
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:39:36
User entered missing code ND - Not Done.	Jiamin Li (b) (4)	01 Feb 2021 10:00:02
DataPoint set to visible.	(b) (4) System	12 Jan 2021 02:42:09

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:08
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:39:36
User entered '38.3' C	Jiamin Li (b) (4)	01 Feb 2021 10:00:02

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:08
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:39:36
User entered 'Other (Other)'	Jiamin Li (b) (4)	01 Feb 2021 10:00:02

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:08
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:39:36
User entered 'Information not specified'	Jiamin Li (b) (4)	01 Feb 2021 10:00:02

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:08
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:39:36
User entered '82'	Jiamin Li (b) (4)	01 Feb 2021 10:00:02

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:08
User entered 'bpm'	System	01 Feb 2021 10:00:02

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:08
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:39:36
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	02 Feb 2021 14:43:53
Query 'Data is required. Please provide.' answered with 'Information not captured.' (Site from System).	Jiamin Li (b) (4)	01 Feb 2021 10:00:15
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Feb 2021 10:00:02
User entered empty.	Jiamin Li (b) (4)	01 Feb 2021 10:00:02

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:08
User entered empty.	System	01 Feb 2021 10:00:02

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:08
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
User closed query 'Per CDM : Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 07:58:01
Query 'Per CDM : Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate' answered with 'Pt has baseline htn. Not an exacerbation' (Site from DM).	Jiamin Li (b) (4)	09 Apr 2021 19:19:22
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:39:36
User opened query 'Per CDM : Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 18:38:14
User entered '170'	Jiamin Li (b) (4)	01 Feb 2021 10:00:02

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:08
User entered 'mmHg'	System	01 Feb 2021 10:00:02

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:08
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:39:36
User entered '89'	Jiamin Li (b) (4)	01 Feb 2021 10:00:02

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:08
User entered 'mmHg'	System	01 Feb 2021 10:00:02

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:08

US3702010

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:08

US3702010

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:19
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:40:14
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Jan 2021 02:42:37

US3702010

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:19
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:40:14
User entered '05 Jan 2021'	Jiamin Li (b) (4)	12 Jan 2021 02:42:37

US3702010

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:17:27

[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 02:37:32
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:40:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 15:35:19
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:45:59

US3702010

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:17:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:37:32
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	06 Feb 2021 01:40:26
User entered '08 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 15:35:19
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:45:59

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:55:30
User entered 'No (N)'	Jiamin Li (b) (4)	17 Mar 2021 19:16:40

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:55:30
User entered empty.	Jiamin Li (b) (4)	17 Mar 2021 19:16:40

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

[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 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:55:30
User entered empty.	Jiamin Li (b) (4)	17 Mar 2021 19:16:40

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:17:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered 'SICKD28'	System	17 Mar 2021 19:16:40

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:55:37
User entered 'No (N)'	Jiamin Li (b) (4)	17 Mar 2021 19:16:46

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:55:37
User entered empty.	Jiamin Li (b) (4)	17 Mar 2021 19:16:46

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:55:37
User entered empty.	Jiamin Li (b) (4)	17 Mar 2021 19:16:46

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered empty.	System	17 Mar 2021 19:16:46

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:55:37
User entered empty.	Jiamin Li (b) (4)	17 Mar 2021 19:16:46

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:55:37
User entered empty.	Jiamin Li (b) (4)	17 Mar 2021 19:16:46

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:55:37
User entered empty.	Jiamin Li (b) (4)	17 Mar 2021 19:16:46

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:55:37
User entered empty.	Jiamin Li (b) (4)	17 Mar 2021 19:16:46

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered empty.	System	17 Mar 2021 19:16:46

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:55:37
User entered empty.	Jiamin Li (b) (4)	17 Mar 2021 19:16:46

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered empty.	System	17 Mar 2021 19:16:46

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:55:37
User entered empty.	Jiamin Li (b) (4)	17 Mar 2021 19:16:46

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered empty.	System	17 Mar 2021 19:16:46

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:55:37
User entered empty.	Jiamin Li (b) (4)	17 Mar 2021 19:16:46

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered empty.	System	17 Mar 2021 19:16:46

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:17:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:55:45
User entered 'No (N)'	Jiamin Li (b) (4)	17 Mar 2021 19:16:50

US3702010

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:17:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:55:45
User entered empty.	Jiamin Li (b) (4)	17 Mar 2021 19:16:50

US3702010

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:17:27

[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 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:55:52
User entered 'No (N)'	Jiamin Li (b) (4)	17 Mar 2021 19:16:56

US3702010

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:17:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:55:52
User entered empty.	Jiamin Li (b) (4)	17 Mar 2021 19:16:56

US3702010

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:17:27

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:06:00
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:50:56

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:43
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 22:48:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 22:48:52
Data point term sent to Coder	System	14 Sep 2020 22:47:46
User entered 'Nausea'	Jiamin Li (b) (4) (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'No (N)'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the corresponding eDiary data for this symptom on this date is noted as NONE. Note that any SAR that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 18:11:28
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the corresponding eDiary data for this symptom on this date is noted as NONE. Note that any SAR that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	28 Sep 2020 21:24:32
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	28 Sep 2020 21:24:28
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES, however, the corresponding eDiary data for this symptom on this date is noted as NONE. Note that any SAR that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 10:50:44
User entered 'Yes (Y)'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'No (N)'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '04 Sep 2020'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 12:08:35
Query 'Data is required. Please provide.' answered with 'Per clinic error, not evaluated.' (Site from System).	Jiamin Li (b) (4)	14 Sep 2020 22:46:55
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 22:46:47
User entered empty.	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User entered empty.	System	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'No (N)'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '11 Sep 2020'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 12:08:39
Query 'Data is required. Please provide.' answered with 'Not evaluated. information not available' (Site from System).	Jiamin Li (b) (4)	14 Sep 2020 22:47:08
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 22:46:47
User entered empty.	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User entered empty.	System	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'No (N)'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Related (RELATED)'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'None (NONE)'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '1'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User entered '0'	System	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25
User entered '0'	System	14 Sep 2020 22:46:47

US3702010

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:17:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:25

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User closed query 'Per DM CLR: Please review this AE as it overlaps with AE#3. Note that for AE with fluctuating severity/seriousness, only one entry should be noted with the highest severity noted. Please reconcile and update eCRF pages as necessary, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 18:11:38
Query 'Per DM CLR: Please review this AE as it overlaps with AE#3. Note that for AE with fluctuating severity/seriousness, only one entry should be noted with the highest severity noted. Please reconcile and update eCRF pages as necessary, otherwise provide clarification.' answered with 'Other field removed' (Site from DM).	Jiamin Li (b) (4)	28 Sep 2020 21:25:37
User opened query 'Per DM CLR: Please review this AE as it overlaps with AE#3. Note that for AE with fluctuating severity/seriousness, only one entry should be noted with the highest severity noted. Please reconcile and update eCRF pages as necessary, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 10:54:12
User coded data point as SOC: General disorders and administration site conditions, HLGHT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 22:52:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 22:52:53
Data point term sent to Coder	System	14 Sep 2020 22:52:01
User entered 'Fatigue'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'No (N)'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User closed query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 03:36:20
Query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification. ' answered with 'AE did not last more than 7 days. Ended on day 7' (Site from DM).	Jiamin Li (b) (4) (b) (4)	24 Nov 2020 21:36:11
User opened query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 05:43:13
User closed query 'Per DM CLR: Please note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol. Please review if recorded event meets criteria, Else consider deleting event as this has been captured in Diary Data. Otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 11:08:43
Query 'Per DM CLR: Please note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol. Please review if recorded event meets criteria, Else consider deleting event as this has been captured in Diary Data. Otherwise provide clarification. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4) (b) (4)	13 Oct 2020 02:59:50
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	13 Oct 2020 02:59:43

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that solicited reactions are only to reported as AE if this meets AE reporting criteria per protocol. Please review if recorded event meets criteria, Else consider deleting event as this has been captured in Diary Data. Otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 14:11:58
User entered 'Yes (Y)'	Jiamin Li (b) (4) (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'No (N)'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '05 Sep 2020'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '20:22'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User entered '05 Sep 2020 20:22'	System	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'No (N)'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '11 Sep 2020'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 12:20:43
Query 'Data is required. Please provide.' answered with 'Not evaluated. Information not available.' (Site from System).	Jiamin Li (b) (4)	14 Sep 2020 22:52:02
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Sep 2020 22:51:55
User entered empty.	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User entered empty.	System	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'No (N)'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Related (RELATED)'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'None (NONE)'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '1'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User entered '0'	System	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29
User entered '0'	System	14 Sep 2020 22:51:55

US3702010

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:17:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:29

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User closed query 'Per DM CLR: Review if this AE is related to the previously recorded AE of FATIGUE (start date 05 SEP 2020). Note that downgrades in intensity are not recorded as separate AEs. The highest grade of the AE remains ongoing until event resolves. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:57:48
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 16:54:57
Query 'Per DM CLR: Review if this AE is related to the previously recorded AE of FATIGUE (start date 05 SEP 2020). Note that downgrades in intensity are not recorded as separate AEs. The highest grade of the AE remains ongoing until event resolves. Review and update eCRF as appropriate. ' answered with 'That AE was not ongoing. We did not know when the event would come back, so we ended that adverse event when the pt reported the event ended. This is a new occurrence separate from the one occurring in september. ' (Site from DM).	Jiamin Li (b) (4)	22 Dec 2020 00:10:56
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Assessed' (Site from DM).	Jiamin Li (b) (4)	22 Dec 2020 00:10:01
User opened query 'Per DM CLR: Review if this AE is related to the previously recorded AE of FATIGUE (start date 05 SEP 2020). Note that downgrades in intensity are not recorded as separate AEs. The highest grade of the AE remains ongoing until event resolves. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 05:41:59
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	07 Nov 2020 01:47:00

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 03:01:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 03:01:26
Data point term sent to Coder	System	13 Oct 2020 03:00:59
User entered 'Fatigue'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'No (N)'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'No (N)'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'No (N)'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '11 Sep 2020'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User entered empty.	System	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'No (N)'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	13 Oct 2020 03:00:38
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	13 Oct 2020 03:00:38
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	13 Oct 2020 03:00:31
User entered '02 Oct 2020'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User entered empty.	System	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'No (N)'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Related (RELATED)'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'None (NONE)'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '1'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jiamin Li (b) (4)	13 Oct 2020 03:00:38
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User entered '0'	System	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17
User entered '0'	System	13 Oct 2020 03:00:31

US3702010

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 10 Jun 2021 09:17:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:17

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain lower, LLT: Lower abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 02:09:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 02:09:31
Data point term sent to Coder	System	27 Oct 2020 02:08:50
User entered 'Lower abdominal pain'	Jiamin Li (b) (4) (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'No (N)'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'No (N)'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'No (N)'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '23 Oct 2020'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User entered empty.	System	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'No (N)'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '26 Oct 2020'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User entered empty.	System	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'No (N)'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'None (NONE)'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '1'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User entered '0'	System	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11
User entered '0'	System	27 Oct 2020 02:08:18

US3702010

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 10 Jun 2021 09:17:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:41:11

US3702010

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:37:55
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'USA-US133-2021-mRNA-1273-P301000001'	System	12 Jan 2021 15:25:00
User entered 'New'	(b) (4), (b) (6)	12 Jan 2021 15:25:00

US3702010

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
User closed query 'For coding purposes, for term COVID-19 SYMPTOMS (ONSET 1/1/2021, DIAGNOSIS 1/5/2021) please specify if this is a Covid-19 infection or something else.' (Site from Coder).	(b) (4), (b) (6)	14 Mar 2021 17:01:33
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
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)	15 Jan 2021 16:11:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Jan 2021 16:11:54
Data point term sent to Coder	System	15 Jan 2021 16:08:43
Query 'For coding purposes, for term COVID-19 SYMPTOMS (ONSET 1/1/2021, DIAGNOSIS 1/5/2021) please specify if this is a Covid-19 infection or something else.' answered with 'Updated' (Site from Coder).	Jiamin Li (b) (4)	15 Jan 2021 16:08:01
Coding entries removed.	Jiamin Li (b) (4)	15 Jan 2021 16:07:57
User entered 'COVID-19 INFECTION (ONSET 1/1/2021, DIAGNOSIS 1/5/2021)' reason for change: Data Entry Error	Jiamin Li (b) (4)	15 Jan 2021 16:07:57
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)	15 Jan 2021 13:20:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Jan 2021 13:20:01
User opened query 'For coding purposes, for term COVID-19 SYMPTOMS (ONSET 1/1/2021, DIAGNOSIS 1/5/2021) please specify if this is a Covid-19 infection or something else.' (Site from Coder).	(b) (4), (b) (6)	12 Jan 2021 18:12:48
Data point term sent to Coder	System	12 Jan 2021 02:38:20

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'COVID-19 Symptoms (Onset 1/1/2021, Jiamin Li diagnosis 1/5/2021)'	(b) (4)	12 Jan 2021 02:38:11

US3702010

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

US3702010

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

US3702010

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

US3702010

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '01 Jan 2021'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

US3702010

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

US3702010

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered empty.	System	12 Jan 2021 02:38:11

US3702010

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:54:08
User closed query 'Per MM, please provide the end date. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 15:10:24
Query 'Per MM, please provide the end date. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	12 Mar 2021 17:11:13
DataPoint Un-verified.	(b) (4)	12 Mar 2021 17:11:03
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 17:11:03
User opened query 'Per MM, please provide the end date. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 21:33:37
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	27 Jan 2021 21:13:31
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 15:06:23
User entered 'Yes (Y)'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

US3702010

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:54:10
DataPoint Un-verified.	Jiamin Li (b) (4)	12 Mar 2021 17:11:03
User entered '25 Feb 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 17:11:03
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty; reason for change Data Entry Error	Jiamin Li (b) (4)	27 Jan 2021 21:13:31
User entered '11 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 15:06:23
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

US3702010

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 19:33:44
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 'Updated' (Site from Safety).	Jiamin Li (b) (4)	26 Jan 2021 15:06:27
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)	21 Jan 2021 17:53:06
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

US3702010

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
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)	18 Mar 2021 14:58:24
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 Feb 2021 16:04:41
User entered empty.	System	12 Jan 2021 02:38:11

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Jiamin Li (b) (4)	27 Jan 2021 21:14:31
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

US3702010

Folder: Adverse Events

Form: Adverse Events (13)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	27 Jan 2021 21:16:44
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	27 Jan 2021 21:14:54
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	27 Jan 2021 21:14:54
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	27 Jan 2021 21:14:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	27 Jan 2021 21:14:54
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	27 Jan 2021 21:14:31
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:54:20
User closed query 'PV Query: Outcome was reported as fatal, please consider adding seriousness criteria of Death. ' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 14:10:37
Query 'PV Query: Outcome was reported as fatal, please consider adding seriousness criteria of Death. ' answered with 'Updated' (Site from Safety).	Jiamin Li (b) (4)	06 Apr 2021 17:57:58
DataPoint Un-verified.	Jiamin Li (b) (4)	06 Apr 2021 17:57:51
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4)	06 Apr 2021 17:57:51
User opened query 'PV Query: Outcome was reported as fatal, please consider adding seriousness criteria of Death. ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 20:48:33
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

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Folder: Adverse Events

Form: Adverse Events (13)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4)	27 Jan 2021 21:16:44
User entered '0'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

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Folder: Adverse Events

Form: Adverse Events (13)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	11 Feb 2021 02:37:28
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'All available information provided. Pt is still in ICU.' (Site from System).	Jiamin Li (b) (4)	01 Feb 2021 09:58:13
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	27 Jan 2021 21:16:44
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4)	27 Jan 2021 21:16:44
User entered '0'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

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Form: Adverse Events (13)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '05 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	27 Jan 2021 21:16:44
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

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Folder: Adverse Events

Form: Adverse Events (13)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
User closed query 'PV Query: Please provide the hospital discharge date, when available. ' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 16:00:49
Query 'PV Query: Please provide the hospital discharge date, when available. ' answered with 'Participant has still not been discharged' (Site from Safety).	Jiamin Li (b) (4)	16 Feb 2021 18:13:02
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User opened query 'PV Query: Please provide the hospital discharge date, when available. ' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 16:06:51
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

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Form: Adverse Events (13)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	27 Jan 2021 21:16:44
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User closed query 'Per CDM: Thank you for your response. Please update once data is available.	(b) (4), (b) (6)	02 Feb 2021 16:27:38
' (Site from DM). Query 'Per CDM: Thank you for your response. Please update once data is available.	Jiamin Li (b) (4) (b) (4)	01 Feb 2021 09:58:45
' answered with 'Pt still in ICU' (Site from DM). User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	29 Jan 2021 14:48:16
User opened query 'Per CDM: Thank you for your response. Please update once data is available.	(b) (4), (b) (6)	29 Jan 2021 14:48:14
' (Site from DM). Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.'	Jiamin Li (b) (4) (b) (4)	27 Jan 2021 21:16:53
answered with 'Participant still in ICU' (Site from System). User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	27 Jan 2021 21:16:44
User entered empty.	Jiamin Li (b) (4) (b) (4)	12 Jan 2021 02:38:11

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

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Folder: Adverse Events

Form: Adverse Events (13)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered 'Not Related (NOT RELATED)'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		15 Jan 2021 16:11:48
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 by data change (Site from System).	System	15 Jan 2021 16:11:48
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jiamin Li (b) (4)	15 Jan 2021 16:11:48
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).	(b) (4)	15 Jan 2021 16:08:35
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	System	15 Jan 2021 16:08:35
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Jiamin Li (b) (4)	15 Jan 2021 16:07:41
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	15 Jan 2021 16:07:41
User entered 'Not Applicable (NOT APPLICABLE)'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11
	(b) (4)	12 Jan 2021 02:38:11

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

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Form: Adverse Events (13)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User closed query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 19:33:53
Query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Updated' (Site from Safety).	Jiamin Li (b) (4)	26 Jan 2021 15:32:31
User opened query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 17:53:35
User entered '1'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:54:36
User closed query 'Per CDM: There is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update accordingly.	(b) (4), (b) (6)	14 Apr 2021 12:08:22
' (Site from DM). Query 'Per CDM: There is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update accordingly.	Jiamin Li (b) (4)	14 Apr 2021 01:46:32
' answered with 'Updated' (Site from DM). DataPoint Un-verified.	Jiamin Li (b) (4)	14 Apr 2021 01:46:28
User entered '1' reason for change: Data Entry Error	Jiamin Li (b) (4)	14 Apr 2021 01:46:28
User opened query 'Per CDM: There is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update accordingly.	(b) (4), (b) (6)	10 Apr 2021 15:02:39
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered '0'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:54:42
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:58:27
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Updated' (Site from Safety).	Jiamin Li (b) (4)	12 Mar 2021 17:11:17
DataPoint Un-verified.	Jiamin Li (b) (4)	12 Mar 2021 17:11:03
User entered 'Fatal (FATAL)' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 17:11:03
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 16:05:13
User closed query 'PV Query: Please provide the symptom log when available.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 19:34:02
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 19:33:59
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jiamin Li (b) (4)	27 Jan 2021 21:13:36
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Jiamin Li (b) (4)	27 Jan 2021 21:13:31
Query 'PV Query: Please provide the symptom log when available.' answered with 'Updated' (Site from Safety).	Jiamin Li (b) (4)	26 Jan 2021 15:32:27

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[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Updated' (Site from Safety).	Jiamin Li (b) (4)	26 Jan 2021 15:06:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 15:06:23
User opened query 'PV Query: Please provide the symptom log when available.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 17:53:47
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 17:52:54
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:38:11

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User closed query 'PV Query: Thank you for your response that information is pending. When available, Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed or is unavailable, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Apr 2021 00:05:07
User closed query 'PV Query: Thank you for your response that information is pending. When available, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results will be available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	24 Apr 2021 00:05:03
Query 'PV Query: Thank you for your response that information is pending. When available, Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed or is unavailable, please state so.' answered with 'Confirmed autopsy was not performed.' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	22 Apr 2021 22:14:42
Query 'PV Query: Thank you for your response that information is pending. When available, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results will be available, please confirm in your response.' answered with 'Lab results sent via email.' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	22 Apr 2021 22:14:22

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Thank you for your response that information is pending. When available, Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed or is unavailable, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:31:26
User opened query 'PV Query: Thank you for your response that information is pending. When available, please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results will be available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 12:31:14
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 22:54:47
User closed query 'Per DM CLR: Narrative = HE HAD RECURRENT SVT. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 18:29:13
User closed query 'Per DM CLR: Narrative = AMIODARONE. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 18:29:11
User closed query 'Per DM CLR: Narrative = CARDIOVERSION. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 18:29:09
User closed query 'Per DM CLR: Narrative = ELECTROLYTE DISTURBANCES. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 18:29:08

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = INTUBATED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 18:28:58
User closed query 'Per DM CLR: Narrative = HI-FLOW OXYGEN AND BI-LEVEL NON-INVASIVE POSITIVE PRESSURE VENTILATION. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 18:28:49
User closed query 'PV Query: PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:37:36
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 17:37:33
Query 'Per DM CLR: Narrative = ELECTROLYTE DISTURBANCES. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Information pending - patient passed away in an external hospital system and we are still trying to obtain medical records and further information.' (Site from DM).	Jiamin Li (b) (4) (b) (4)	09 Apr 2021 19:07:39
Query 'Per DM CLR: Narrative = CARDIOVERSION. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Information pending - patient passed away in an external hospital system and we are still trying to obtain medical records and further information.' (Site from DM).	Jiamin Li (b) (4) (b) (4)	09 Apr 2021 19:07:27

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = AMIODARONE. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Information pending - patient passed away in an external hospital system and we are still trying to obtain medical records and further information.' (Site from DM).	Jiamin Li (b) (4) (b) (4)	09 Apr 2021 19:07:01
Query 'Per DM CLR: Narrative = HE HAD RECURRENT SVT. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'Information pending - patient passed away in an external hospital system and we are still trying to obtain medical records and further information.' (Site from DM).	Jiamin Li (b) (4) (b) (4)	09 Apr 2021 19:06:46
Query 'PV Query: PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so' answered with 'Information pending - patient passed away in an external hospital system and we are still trying to obtain medical records and further information.' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	09 Apr 2021 19:06:23
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'Information pending - patient passed away in an external hospital system and we are still trying to obtain medical records and further information.' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	09 Apr 2021 19:06:00
User closed query 'PV Query: please confirm that dates in narrative occurred in 2021 (vs 2020 as reported) ' (Site from Safety).	(b) (4), (b) (6) (b) (6)	07 Apr 2021 14:10:29
Query 'Per DM CLR: Narrative = INTUBATED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4) (b) (4)	06 Apr 2021 18:02:32

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = HI-FLOW OXYGEN AND BI-LEVEL NON-INVASIVE POSITIVE PRESSURE VENTILATION. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	06 Apr 2021 18:02:24
Query 'PV Query: please confirm that dates in narrative occurred in 2021 (vs 2020 as reported) ' answered with 'Date is 2021' (Site from Safety).	Jiamin Li (b) (4)	06 Apr 2021 18:00:12

US3702010

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT WAS HOSPITALIZED 1/5-1/11/21 FOR COVID-19 (DX 1/5/21). HE WAS HYPOXIC WITH AMBULATION (O2 SAT 89%) BUT OTHERWISE MEDICALLY STABLE WITH NO END ORGAN DAMAGE. HE DID NOT REQUIRE ICU OR MECHANICAL VENTILATION. HE RECEIVED IV REMDESIVIR AND DEXAMETHASONE FOR TREATMENT. PARTICIPANT WAS SEEN ON 1/5/21 FOR SYMPTOMS SUGGESTIVE OF COVID INCLUDING FEVER, COUGH, AND DYSPNEA ON EXERTION. HE REPORTED 1/1 AS THE FIRST SX ONSET. AT VISIT, PT WAS NOTED TO BE COUGHING AND SHORT OF BREATH WITH EXERTION AND EMS WAS CALLED. COVID PNEUMONIA WAS DIAGNOSED (PULMONARY INFILTRATES, HYPOXEMIA, AND PCR POSITIVE FOR SARS-COV2. HE WAS RE-HOSPITALIZED 1/11-1/15/21 AND TREATED WITH REMDESIVIR (5-DAY COURSE) AND DEXAMETHASONE.ONCE HOME HE WAS STABLE UNTIL HE DISCONTINUED DEXAMETHASONE ON 1/16. HE THEN NOTED FEVERS AND WORSENING HYPOXIA AND SHORTNESS OF BREATH AND CALLED EMS ON 1/20/21. PT ADMITTED ON 1/20/21 FOR ACUTE RESPIRATORY FAILURE SECONDARY TO PNEUMONIA REQUIRING HI-FLOW OXYGEN AND BI-LEVEL NON-INVASIVE POSITIVE PRESSURE VENTILATION. DESPITE REINSTITUTION OF STEROIDS, EMPIRIC TREATMENT FOR BACTERIAL PNEUMONIA AND EMPIRIC COVERAGE FOR PNEUMOCYSTIS JIROVECI PNEUMONIA, PT DEVELOPED WORSENING HYPOXEMIA AND WAS INTUBATED ON 1/24 AND TRANSFERRED TO MICU. DURING HIS STAY HE WAS SEDATED AND PARALYZED ON MECHANICAL VENTILATION WITH HIGH VENT REQUIREMENTS, WITH PERSISTENT HYPOXEMIA. HE HAD RECURRENT SVT	Jiamin Li (b) (4)	06 Apr 2021 18:00:06

US3702010

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[Narrative](#)

Audit	User	Time (GMT)
TREATED WITH AMIODARONE AND CARDIOVERSION, AS WELL AS ELECTROLYTE DISTURBANCES. WORK UP REVEALED NO OTHER MICROBIAL EXPLANATION FOR PNEUMONIA/ARDS OTHER THAN SARS-COVW2 (PT REMAINED PCR POSITIVE ON 1/31/21 AND 2/25/21). AFTER SEVERAL WEEKS WITH NO IMPROVEMENT AND GIVEN THE SEVERITY OF HIS LUNG DAMAGE, HIS FAMILY ELECTED TO SIGN A DO NOT RESUSCITATE ORDER. ON 2/25/21 HE DIED FROM THE ARDS WITH ONLY IDENTIFIED CAUSATIVE ORGANISM BEING SARS-COV2. THE PI DETERMINATION OF CAUSE OF DEATH IS ARDS DUE TO COVID.'		
reason for change: Data Entry Error User opened query 'Per DM CLR: Narrative = ELECTROLYTE DISTURBANCES. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 01:46:12
User opened query 'Per DM CLR: Narrative = CARDIOVERSION. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 01:46:06
User opened query 'Per DM CLR: Narrative = AMIODARONE. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 01:46:01
User opened query 'Per DM CLR: Narrative = HE HAD RECURRENT SVT. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 01:45:55
User opened query 'Per DM CLR: Narrative = INTUBATED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 01:45:49

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = HI-FLOW OXYGEN AND BI-LEVEL NON-INVASIVE POSITIVE PRESSURE VENTILATION. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	27 Mar 2021 01:45:44
User opened query 'PV Query: please confirm that dates in narrative occurred in 2021 (vs 2020 as reported) ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 20:48:55
User opened query 'PV Query: PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 20:48:44
User closed query 'PV Query: Please provide clarification on hospital admission and discharge dates; conflicting information reported: (1) admission 05 Jan 2021 with no discharge date, (2) admission 11 Jan 2021, discharge 15 Jan 2021, (3) admission 20 Jan 2021. ' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 15:58:36
DataPoint Un-verified.	Jiamin Li (b) (4) (b) (4)	12 Mar 2021 17:11:03

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Pt was hospitalized 1/5-1/11/20 for COVID-19 (dx 1/5/20). He was hypoxic with ambulation (O2 sat 89%) but otherwise medically stable with no end organ damage. He did not require ICU or mechanical ventilation. He received IV remdesivir and dexamethasone for treatment. Participant was seen on 1/5/21 for symptoms suggestive of COVID including fever, cough, and dyspnea on exertion. He reported 1/1 as the first sx onset. At visit, pt was noted to be coughing and short of breath with exertion and EMS was called. COVID pneumonia was diagnosed (pulmonary infiltrates, hypoxemia, and PCR positive for SARS-CoV2. He was re-hospitalized 1/11-1/15/21 and treated with remdesivir (5-day course) and dexamethasone. Once home he was stable until he discontinued dexamethasone on 1/16. He then noted fevers and worsening hypoxia and shortness of breath and called EMS on 1/20/21. Pt admitted on 1/20/21 for acute respiratory failure secondary to pneumonia requiring hi-flow oxygen and bi-level non-invasive positive pressure ventilation. Despite reinstitution of steroids, empiric treatment for bacterial pneumonia and empiric coverage for Pneumocystis jiroveci pneumonia, pt developed worsening hypoxemia and was intubated on 1/24 and transferred to MICU. During his stay he was sedated and paralyzed on mechanical ventilation with high vent requirements, with persistent hypoxemia. He had recurrent SVT treated with amiodarone and cardioversion, as well as electrolyte disturbances. Work up revealed no other microbial explanation for pneumonia/ARDS other than SARS-CoVw2 (pt remained PCR positive on 1/31/21 and 2/25/21). After several weeks with no improvement and given the severity of his lung damage, his family elected to sign a do not resuscitate order. On 2/25/21 he died from the ARDS with only identified causative organism being SARS-CoV2. The PI determination of cause of death is ARDS due to COVID.' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	12 Mar 2021 17:11:03

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide clarification on hospital admission and discharge dates; conflicting information reported: (1) admission 05 Jan 2021 with no discharge date, (2) admission 11 Jan 2021, discharge 15 Jan 2021, (3) admission 20 Jan 2021. ' answered with 'Pt was re-hospitalized.' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	12 Mar 2021 17:06:35
User closed query 'PV Query: Please confirm whether a second dose of blinded study vaccine was administered, and if second dose of blinded study vaccine not administered, please provide reason for discontinuation of dosing. ' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 16:01:04
User closed query 'PV Query: Please consider whether the event of respiratory failure meets reporting criteria for SAE considering the need for hospitalization, ICU admission, and mechanical ventilation, and update report if appropriate. ' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 16:00:57
Query 'PV Query: Please confirm whether a second dose of blinded study vaccine was administered, and if second dose of blinded study vaccine not administered, please provide reason for discontinuation of dosing. ' answered with 'Second dose was not administered because pt refused. ' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	16 Feb 2021 18:17:11
Query 'PV Query: Please consider whether the event of respiratory failure meets reporting criteria for SAE considering the need for hospitalization, ICU admission, and mechanical ventilation, and update report if appropriate. ' answered with 'This report has already indicated that the event is serious, with specific criteria marked.' (Site from Safety).	Jiamin Li (b) (4) (b) (4)	16 Feb 2021 18:16:37
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:07:29
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 16:07:12

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm whether a second dose of blinded study vaccine was administered, and if second dose of blinded study vaccine not administered, please provide reason for discontinuation of dosing. ' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 16:06:36
User opened query 'PV Query: Please consider whether the event of respiratory failure meets reporting criteria for SAE considering the need for hospitalization, ICU admission, and mechanical ventilation, and update report if appropriate. ' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 16:06:23
User opened query 'PV Query: Please provide clarification on hospital admission and discharge dates; conflicting information reported: (1) admission 05 Jan 2021 with no discharge date, (2) admission 11 Jan 2021, discharge 15 Jan 2021, (3) admission 20 Jan 2021. ' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 16:05:40
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	01 Feb 2021 09:58:33
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	01 Feb 2021 09:58:33

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Participant was seen on 1/5/21 for symptoms suggestive of COVID including fever, cough and dysnea on exertion. He reported 1/1 as the first symptom onset. At that visit he was noted to be coughing and short of breath with exertion and EMS was called. He was hospitalized 1/11-1/15/21 and treated with remdesivir (5 day course) and steroids. He improved and was discharged. Once home he was stable until he discontinued steroids on 1/16. Subsequently he noted fevers and worsening hypoxia and shortness of breath and called EMS on 1/20/20. He was taken to hospital and received steroids, TMP-SMZ and azithromycin and high flow oxygen until 1/23 when he required ICU transfer for mechanical ventilation for hypoxia and low dose pressors for blood pressure support in the setting of sedation. Work up to date reveals no diagnosis outside of COVID-19 to explain his respiratory failure. He remains in ICU on mechanical ventilation and low dose pressors.' reason for change: Data Entry Error	Jiamin Li (b) (4) (b) (4)	01 Feb 2021 09:58:33
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	27 Jan 2021 21:14:54
User entered empty.	Jiamin Li (b) (4) (b) (4)	12 Jan 2021 02:38:11

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '1'	System	27 Jan 2021 21:14:54
User entered '0'	System	12 Jan 2021 02:38:11

US3702010

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '1'	System	12 Jan 2021 02:38:11

US3702010

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 10 Jun 2021 09:17:27

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '1'	System	27 Jan 2021 21:16:44

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:17:27

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:10:07
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:42:33

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:35
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: AZELASTINE HYDROCHLORIDE, PRODUCTSYNONYM: AZELASTINE HCL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 05:37:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 05:37:39
Data point term sent to Coder	System	08 Sep 2020 22:44:03
User entered 'Azelastine HCl 0.05%'	Jiamin Li (b) (4)	08 Sep 2020 22:43:15

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:37
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:43:15

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:39
Query 'Per DM CLR: Please update the indication to reflect the location and type of allergies. Review and update indication and ensure to update MH eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 12:54:22
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of allergies. Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 19:04:13
User entered 'Allergies'	Jiamin Li (b) (4)	08 Sep 2020 22:43:15

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:42
User entered 'Unknown'	Jiamin Li (b) (4)	08 Sep 2020 22:43:15

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:45
User entered 'Other (OTHER)'	Jiamin Li (b) (4)	08 Sep 2020 22:43:15

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:47
User entered 'Unknown'	Jiamin Li (b) (4)	08 Sep 2020 22:43:15

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:49
User entered 'unknown (UNKNOWN)'	Jiamin Li (b) (4)	08 Sep 2020 22:43:15

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:51
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:43:15

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:53
User entered 'Other (OTHER)'	Jiamin Li (b) (4)	08 Sep 2020 22:43:15

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:55
User entered 'Unknown'	Jiamin Li (b) (4)	08 Sep 2020 22:43:15

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:56
User entered '24 Sep 2018'	Jiamin Li (b) (4)	08 Sep 2020 22:43:15

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:58
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:43:15

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:21:00
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:43:15

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:21:02
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:43:15

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:21:06
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:43:15

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered empty.	System	08 Sep 2020 22:43:15

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered empty.	System	08 Sep 2020 22:43:15

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered empty.	System	08 Sep 2020 22:43:15

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: BICTEGRAVIR SODIUM;EMTRICITABINE;TENOFVIR ALAFENAMIDE FUMARATE, PRODUCTSYNONYM: BIKTARVY - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Sep 2020 06:52:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	10 Sep 2020 06:52:38
Data point term sent to Coder	System	08 Sep 2020 22:44:03
User entered 'Bictegravir-emtricitabine-tenofovir Alafenamide (Biktarvy) 50-200-25mg'	Jiamin Li (b) (4)	08 Sep 2020 22:43:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:05
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:43:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:07
User entered 'HIV'	Jiamin Li (b) (4)	08 Sep 2020 22:43:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:08
User entered '1'	Jiamin Li (b) (4)	08 Sep 2020 22:43:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:10
User entered 'tablet (TABLET)'	Jiamin Li (b) (4)	08 Sep 2020 22:43:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:11
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:43:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:14
User entered 'once daily (QD)'	Jiamin Li (b) (4)	08 Sep 2020 22:43:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:16
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:43:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:18
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	08 Sep 2020 22:43:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:21
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:43:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:23
User entered '20 Apr 2020'	Jiamin Li (b) (4)	08 Sep 2020 22:43:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:24
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:43:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:29
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:43:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:27
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:43:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:20:31
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:43:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '1'	System	08 Sep 2020 22:43:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '1'	System	08 Sep 2020 22:43:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '804 (804)'	System	08 Sep 2020 22:43:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 06:17:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 06:17:41
Data point term sent to Coder	System	08 Sep 2020 22:45:04
User entered 'Bisacodyl 5mg'	Jiamin Li (b) (4)	08 Sep 2020 22:44:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:24
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:44:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:26
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 17:46:31
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. answered with 'Recorded.' (Site from DM).	Jiamin Li (b) (4)	22 Dec 2020 00:11:18
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:05:38
User entered 'constipation'	Jiamin Li (b) (4)	08 Sep 2020 22:44:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:29
User entered '2'	Jiamin Li (b) (4)	08 Sep 2020 22:44:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:31
User entered 'tablet (TABLET)'	Jiamin Li (b) (4)	08 Sep 2020 22:44:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:33
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:44:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:34
User entered 'once daily (QD)'	Jiamin Li (b) (4)	08 Sep 2020 22:44:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:37
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:44:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:40
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	08 Sep 2020 22:44:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:42
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:44:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:45
User entered '28 Apr 2016'	Jiamin Li (b) (4)	08 Sep 2020 22:44:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:48
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:44:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:51
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:44:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:54
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:44:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:57
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:44:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '1'	System	08 Sep 2020 22:44:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '1'	System	08 Sep 2020 22:44:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '804 (804)'	System	08 Sep 2020 22:44:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:49
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: IMIDAZOLE AND TRIAZOLE DERIVATIVES, PRODUCT: CLOTRIMAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 00:05:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 00:05:54
Data point term sent to Coder	System	08 Sep 2020 22:46:04
User entered 'Clotrimazole 1% Cream'	Jiamin Li (b) (4) (b) (4)	08 Sep 2020 22:45:08

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:51
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:45:08

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:52
User entered 'Unknown'	Jiamin Li (b) (4)	08 Sep 2020 22:45:08

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:54
User entered 'Unknown'	Jiamin Li (b) (4)	08 Sep 2020 22:45:08

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:56
User entered 'Other (OTHER)'	Jiamin Li (b) (4)	08 Sep 2020 22:45:08

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:59
User entered 'Unknown'	Jiamin Li (b) (4)	08 Sep 2020 22:45:08

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:01
User entered 'twice daily (BID)'	Jiamin Li (b) (4)	08 Sep 2020 22:45:08

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:04
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:45:08

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:07
User entered 'Topical (TOPICAL)'	Jiamin Li (b) (4)	08 Sep 2020 22:45:08

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:09
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:45:08

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:11
User entered '12 Nov 2018'	Jiamin Li (b) (4)	08 Sep 2020 22:45:08

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:13
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:45:08

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:14
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:45:08

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:16
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:45:08

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:19:18
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:45:08

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '2'	System	08 Sep 2020 22:45:08

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '1'	System	08 Sep 2020 22:45:08

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '804 (804)'	System	08 Sep 2020 22:45:08

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 00:47:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 00:47:57
Data point term sent to Coder	System	08 Sep 2020 22:46:04
User entered 'Escitalopram 5mg'	Jiamin Li (b) (4)	08 Sep 2020 22:45:33

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:04
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:45:33

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 12:54:45
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4) (b) (4)	09 Mar 2021 17:12:27
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:06
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:05:48
User entered 'Depression'	Jiamin Li (b) (4) (b) (4)	08 Sep 2020 22:45:33

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:10
User entered '1'	Jiamin Li (b) (4)	08 Sep 2020 22:45:33

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:13
User entered 'tablet (TABLET)'	Jiamin Li (b) (4)	08 Sep 2020 22:45:33

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:15
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:45:33

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:20
User entered 'once daily (QD)'	Jiamin Li (b) (4)	08 Sep 2020 22:45:33

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:22
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:45:33

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:25
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	08 Sep 2020 22:45:33

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:32
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:45:33

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:38
User entered '20 Apr 2020'	Jiamin Li (b) (4)	08 Sep 2020 22:45:33

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:39
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:45:33

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:41
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:45:33

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:42
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:45:33

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:18:44
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:45:33

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '1'	System	08 Sep 2020 22:45:33

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '1'	System	08 Sep 2020 22:45:33

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '804 (804)'	System	08 Sep 2020 22:45:33

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:17:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Oct 2020 19:36:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	13 Oct 2020 19:36:19
Data point term sent to Coder	System	13 Oct 2020 19:36:07
Coding entries removed.	Jiamin Li (b) (4)	13 Oct 2020 19:35:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 07:10:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 07:10:38
Data point term sent to Coder	System	08 Sep 2020 22:46:05
User entered 'Multiple vitamin'	Jiamin Li (b) (4)	08 Sep 2020 22:46:00

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:20
User closed query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 18:02:12
Query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	22 Dec 2020 00:12:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	22 Dec 2020 00:12:06
User opened query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 04:07:07
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:46:00

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:26
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 15:12:40
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'Updated' (Site from DM).	Jiamin Li (b) (4)	13 Oct 2020 19:35:18
User entered 'Nutritional supplement' reason for change: Data Entry Error	Jiamin Li (b) (4)	13 Oct 2020 19:35:15
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 08:06:13
User entered 'Vitamin and/or mineral deficiency'	Jiamin Li (b) (4)	08 Sep 2020 22:46:00

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:27
User entered '1'	Jiamin Li (b) (4)	08 Sep 2020 22:46:00

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:29
User entered 'tablet (TABLET)'	Jiamin Li (b) (4)	08 Sep 2020 22:46:00

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:31
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:46:00

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:35
User entered 'once daily (QD)'	Jiamin Li (b) (4)	08 Sep 2020 22:46:00

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:37
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:46:00

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:40
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	08 Sep 2020 22:46:00

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:43
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:46:00

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:46
User entered '20 Apr 2020'	Jiamin Li (b) (4)	08 Sep 2020 22:46:00

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:48
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:46:00

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:52
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:46:00

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:54
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:46:00

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:56
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:46:00

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '1'	System	08 Sep 2020 22:46:00

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '1'	System	08 Sep 2020 22:46:00

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '804 (804)'	System	08 Sep 2020 22:46:00

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:17:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 06:34:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 06:34:44
Data point term sent to Coder	System	08 Sep 2020 22:47:06
User entered 'Pantoprazole 20mg'	Jiamin Li (b) (4)	08 Sep 2020 22:46:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:41
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:46:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:44
User entered 'Esophageal varices, portal hypertensive gastropathy'	Jiamin Li (b) (4)	08 Sep 2020 22:46:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:47
User entered '1'	Jiamin Li (b) (4)	08 Sep 2020 22:46:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:50
User entered 'tablet (TABLET)'	Jiamin Li (b) (4)	08 Sep 2020 22:46:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:52
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:46:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:54
User entered 'once daily (QD)'	Jiamin Li (b) (4)	08 Sep 2020 22:46:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:56
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:46:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:59
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	08 Sep 2020 22:46:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:00
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:46:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:02
User entered '20 Apr 2020'	Jiamin Li (b) (4)	08 Sep 2020 22:46:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:05
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:46:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:07
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:46:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:10
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:46:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:17:12
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:46:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '1'	System	08 Sep 2020 22:46:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '1'	System	08 Sep 2020 22:46:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '804 (804)'	System	08 Sep 2020 22:46:27

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:17:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR HYDROCHLORIDE, PRODUCTSYNONYM: VALACYCLOVIR HCL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 03:25:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Sep 2020 03:25:42
Data point term sent to Coder	System	08 Sep 2020 22:47:05
User entered 'Valacyclovir HCl 1g'	Jiamin Li (b) (4)	08 Sep 2020 22:46:57

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:56
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:46:57

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:57
User entered 'HSV'	Jiamin Li (b) (4)	08 Sep 2020 22:46:57

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:59
User entered '1'	Jiamin Li (b) (4)	08 Sep 2020 22:46:57

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:03
User entered 'tablet (TABLET)'	Jiamin Li (b) (4)	08 Sep 2020 22:46:57

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:06
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:46:57

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:10
User entered 'other (OTHER)'	Jiamin Li (b) (4)	08 Sep 2020 22:46:57

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:12
User entered 'Every 12 hours'	Jiamin Li (b) (4)	08 Sep 2020 22:46:57

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:14
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	08 Sep 2020 22:46:57

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:16
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:46:57

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:22
User entered '07 Jun 2017'	Jiamin Li (b) (4)	08 Sep 2020 22:46:57

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:24
User entered '0'	Jiamin Li (b) (4)	08 Sep 2020 22:46:57

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:29
User entered 'Yes (Y)'	Jiamin Li (b) (4)	08 Sep 2020 22:46:57

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:31
User entered empty.	Jiamin Li (b) (4)	08 Sep 2020 22:46:57

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:16:33
User entered 'No (N)'	Jiamin Li (b) (4)	08 Sep 2020 22:46:57

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered empty.	System	08 Sep 2020 22:46:57

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered empty.	System	08 Sep 2020 22:46:57

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered empty.	System	08 Sep 2020 22:46:57

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:17:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:33
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Dec 2020 11:48:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Dec 2020 11:48:44
Data point term sent to Coder	System	22 Dec 2020 00:19:48
User entered 'Influenza Vaccine (Flulaval)'	Jiamin Li (b) (4)	22 Dec 2020 00:19:24

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:33
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:18
User entered 'Yes (Y)'	Jiamin Li (b) (4)	22 Dec 2020 00:19:24

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:33
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:20
User entered 'Influenza Prophylaxis'	Jiamin Li (b) (4)	22 Dec 2020 00:19:24

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:33
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:23
User entered 'unknown'	Jiamin Li (b) (4)	22 Dec 2020 00:19:24

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:33
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:25
User entered 'Other (OTHER)'	Jiamin Li (b) (4)	22 Dec 2020 00:19:24

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:33
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:28
User entered 'unknown'	Jiamin Li (b) (4)	22 Dec 2020 00:19:24

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:33
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:30
User entered 'once (ONCE)'	Jiamin Li (b) (4)	22 Dec 2020 00:19:24

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:33
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:32
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:19:24

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:33
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:34
User entered 'Intramuscular (INTRAMUSCULAR)'	Jiamin Li (b) (4)	22 Dec 2020 00:19:24

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:33
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:36
User entered empty.	Jiamin Li (b) (4)	22 Dec 2020 00:19:24

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:33
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:38
User entered '02 Oct 2020'	Jiamin Li (b) (4)	22 Dec 2020 00:19:24

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:33
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:41
User entered '0'	Jiamin Li (b) (4)	22 Dec 2020 00:19:24

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:33
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:44
User entered 'No (N)'	Jiamin Li (b) (4)	22 Dec 2020 00:19:24

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:33
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:46
User entered '02 Oct 2020'	Jiamin Li (b) (4)	22 Dec 2020 00:19:24

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:33
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:49
User entered 'No (N)'	Jiamin Li (b) (4)	22 Dec 2020 00:19:24

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:33
User entered empty.	System	22 Dec 2020 00:19:24

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:33
User entered empty.	System	22 Dec 2020 00:19:24

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:33
User entered empty.	System	22 Dec 2020 00:19:24

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:17:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:39
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:38
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 15:27:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Jan 2021 15:27:54
Data point term sent to Coder	System	12 Jan 2021 02:39:20
User entered 'Ibuprofen'	Jiamin Li (b) (4) (b) (4)	12 Jan 2021 02:39:07

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:39
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:39
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:39:07

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:39
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:41
User entered 'Fever (COVID-19 symptoms)'	Jiamin Li (b) (4)	12 Jan 2021 02:39:07

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:39
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:43
User entered '400'	Jiamin Li (b) (4)	12 Jan 2021 02:39:07

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:39
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:44
User entered 'mg (mg)'	Jiamin Li (b) (4)	12 Jan 2021 02:39:07

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:39
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:53
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:39:07

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:39
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:55
User entered 'once daily (QD)'	Jiamin Li (b) (4)	12 Jan 2021 02:39:07

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:39
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:56
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:39:07

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:39
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:58
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	12 Jan 2021 02:39:07

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:39
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:01
User entered empty.	Jiamin Li (b) (4)	12 Jan 2021 02:39:07

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:39
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:03
User entered '02 Jan 2021'	Jiamin Li (b) (4)	12 Jan 2021 02:39:07

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:39
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:05
User entered '0'	Jiamin Li (b) (4)	12 Jan 2021 02:39:07

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:39
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:07
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:39:07

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:39
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:09
User entered '03 Jan 2021'	Jiamin Li (b) (4)	12 Jan 2021 02:39:07

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:39
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:15:11
User entered 'No (N)'	Jiamin Li (b) (4)	12 Jan 2021 02:39:07

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:39
User entered '1'	System	12 Jan 2021 02:39:07

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:39
User entered '1'	System	12 Jan 2021 02:39:07

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:39
User entered '804 (804)'	System	12 Jan 2021 02:39:07

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:17:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:44
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 11:59:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 11:59:08
Data point term sent to Coder	System	26 Jan 2021 15:09:41
User entered 'Ceftriaxone'	Jiamin Li (b) (4)	26 Jan 2021 15:08:52

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:44
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:08:52

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:44
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Fever (related to COVID-19)'	Jiamin Li (b) (4)	26 Jan 2021 15:08:52

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:44
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '2'	Jiamin Li (b) (4)	26 Jan 2021 15:08:52

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:44
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'g (g)'	Jiamin Li (b) (4)	26 Jan 2021 15:08:52

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:44
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:08:52

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:44
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'once daily (QD)'	Jiamin Li (b) (4)	26 Jan 2021 15:08:52

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:44
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:08:52

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:44
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Intravenous (INTRAVENOUS)'	Jiamin Li (b) (4)	26 Jan 2021 15:08:52

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:44
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:08:52

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:44
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '05 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:08:52

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:44
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 15:08:52

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:44
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:08:52

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:44
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '05 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:08:52

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:44
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:08:52

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:44
User entered '1'	System	26 Jan 2021 15:08:52

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:44
User entered '1'	System	26 Jan 2021 15:08:52

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:44
User entered '804 (804)'	System	26 Jan 2021 15:08:52

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:17:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:46
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 00:18:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 00:18:54
Data point term sent to Coder	System	26 Jan 2021 15:09:41
User entered 'Remdesevir'	Jiamin Li (b) (4)	26 Jan 2021 15:09:21

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:46
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:09:21

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:46
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'COVID-19'	Jiamin Li (b) (4)	26 Jan 2021 15:09:21

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:46
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '200'	Jiamin Li (b) (4)	26 Jan 2021 15:09:21

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:46
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'mg (mg)'	Jiamin Li (b) (4)	26 Jan 2021 15:09:21

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:46
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:09:21

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:46
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'once daily (QD)'	Jiamin Li (b) (4)	26 Jan 2021 15:09:21

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:46
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:09:21

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:46
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Intravenous (INTRAVENOUS)'	Jiamin Li (b) (4)	26 Jan 2021 15:09:21

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:46
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:09:21

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:46
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '05 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:09:21

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:17:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:46
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 15:09:21

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:46
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:09:21

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:46
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '05 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:09:21

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:46
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:09:21

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:46
User entered '1'	System	26 Jan 2021 15:09:21

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:46
User entered '1'	System	26 Jan 2021 15:09:21

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:46
User entered '804 (804)'	System	26 Jan 2021 15:09:21

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:17:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:53
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 15:12:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 15:12:13
Data point term sent to Coder	System	26 Jan 2021 15:11:44
User entered 'Dexamethasone'	Jiamin Li (b) (4)	26 Jan 2021 15:11:11

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:53
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:11:11

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:53
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'COVID-19'	Jiamin Li (b) (4)	26 Jan 2021 15:11:11

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:53
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '10'	Jiamin Li (b) (4)	26 Jan 2021 15:11:11

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:53
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'mg (mg)'	Jiamin Li (b) (4)	26 Jan 2021 15:11:11

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:53
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:11:11

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:53
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'once daily (QD)'	Jiamin Li (b) (4)	26 Jan 2021 15:11:11

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:53
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:11:11

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:53
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	26 Jan 2021 15:11:11

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:53
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:11:11

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:53
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '05 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 17:42:01
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:11:11

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:53
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 17:42:01
User entered '1'	Jiamin Li (b) (4)	26 Jan 2021 15:11:11

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:53
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:11:11

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:53
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Mar 2021 17:42:01
User entered '16 Jan 2021' reason for change: Data Entry Error	Jiamin Li (b) (4)	12 Mar 2021 17:42:01
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	26 Jan 2021 15:11:11
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:11:11

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:53
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:11:11

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:53
User entered '1'	System	26 Jan 2021 15:11:11

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:53
User entered '1'	System	26 Jan 2021 15:11:11

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:53
User entered '804 (804)'	System	26 Jan 2021 15:11:11

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:17:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: REMDESIVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 00:18:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 00:18:54
Data point term sent to Coder	System	26 Jan 2021 15:12:45
User entered 'Remdesevir'	Jiamin Li (b) (4)	26 Jan 2021 15:12:14

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:12:14

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'COVID-19'	Jiamin Li (b) (4)	26 Jan 2021 15:12:14

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '100'	Jiamin Li (b) (4)	26 Jan 2021 15:12:14

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'mg (mg)'	Jiamin Li (b) (4)	26 Jan 2021 15:12:14

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:12:14

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'once daily (QD)'	Jiamin Li (b) (4)	26 Jan 2021 15:12:14

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:12:14

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Intravenous (INTRAVENOUS)'	Jiamin Li (b) (4)	26 Jan 2021 15:12:14

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:12:14

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '06 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:12:14

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:17:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 15:12:14

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:12:14

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '09 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:12:14

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:54
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:12:14

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:54
User entered '1'	System	26 Jan 2021 15:12:14

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:54
User entered '1'	System	26 Jan 2021 15:12:14

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:54
User entered '804 (804)'	System	26 Jan 2021 15:12:14

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:17:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:56
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 15:14:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 15:14:09
Data point term sent to Coder	System	26 Jan 2021 15:13:47
User entered 'Lovenox'	Jiamin Li (b) (4)	26 Jan 2021 15:12:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:56
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:12:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:56
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'COVID-19'	Jiamin Li (b) (4)	26 Jan 2021 15:12:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:56
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '40'	Jiamin Li (b) (4)	26 Jan 2021 15:12:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:56
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'mg (mg)'	Jiamin Li (b) (4)	26 Jan 2021 15:12:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:56
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:12:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:56
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'once daily (QD)'	Jiamin Li (b) (4)	26 Jan 2021 15:12:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:56
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:12:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:56
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jiamin Li (b) (4)	26 Jan 2021 15:12:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:56
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:12:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:56
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '05 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:12:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:56
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 15:12:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:56
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:12:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:56
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '11 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:12:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:56
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:12:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:56
User entered '1'	System	26 Jan 2021 15:12:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:56
User entered '1'	System	26 Jan 2021 15:12:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:56
User entered '804 (804)'	System	26 Jan 2021 15:12:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:17:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 00:28:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 00:28:56
Data point term sent to Coder	System	26 Jan 2021 15:13:47
User entered 'Motrin'	Jiamin Li (b) (4) (b) (4)	26 Jan 2021 15:13:22

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:13:22

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'COVID-19'	Jiamin Li (b) (4)	26 Jan 2021 15:13:22

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '600'	Jiamin Li (b) (4)	26 Jan 2021 15:13:22

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'mg (mg)'	Jiamin Li (b) (4)	26 Jan 2021 15:13:22

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:13:22

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'once daily (QD)'	Jiamin Li (b) (4)	26 Jan 2021 15:13:22

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:13:22

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	26 Jan 2021 15:13:22

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:13:22

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '05 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:13:22

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:17:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 15:13:22

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:13:22

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '05 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:13:22

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:59
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:13:22

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:59
User entered '1'	System	26 Jan 2021 15:13:22

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:59
User entered '1'	System	26 Jan 2021 15:13:22

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:23:59
User entered '804 (804)'	System	26 Jan 2021 15:13:22

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:17:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:22:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE, PRODUCTSYNONYM: TESSALON PERLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Jan 2021 15:16:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Jan 2021 15:16:13
Data point term sent to Coder	System	26 Jan 2021 15:15:50
User entered 'Tessalon Perle'	Jiamin Li (b) (4)	26 Jan 2021 15:14:54

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:22:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:14:54

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:22:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'COVID-19'	Jiamin Li (b) (4)	26 Jan 2021 15:14:54

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:22:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '100'	Jiamin Li (b) (4)	26 Jan 2021 15:14:54

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:22:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'mg (mg)'	Jiamin Li (b) (4)	26 Jan 2021 15:14:54

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:22:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:14:54

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:22:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'twice daily (BID)'	Jiamin Li (b) (4)	26 Jan 2021 15:14:54

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:22:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:14:54

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:22:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Other (OTHER)'	Jiamin Li (b) (4)	26 Jan 2021 15:14:54

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:22:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Unknown'	Jiamin Li (b) (4)	26 Jan 2021 15:14:54

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:22:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '06 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:14:54

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:17:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:22:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 15:14:54

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:22:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:14:54

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:22:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '11 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:14:54

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:22:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:14:54

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:22:34
User entered '2'	System	26 Jan 2021 15:14:54

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:22:34
User entered '1'	System	26 Jan 2021 15:14:54

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:22:34
User entered '804 (804)'	System	26 Jan 2021 15:14:54

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:17:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:38
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 15:16:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 15:16:14
Data point term sent to Coder User entered 'Melatonin'	System Jiamin Li (b) (4)	26 Jan 2021 15:15:48 26 Jan 2021 15:15:20

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:38
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:15:20

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:38
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Insomnia'	Jiamin Li (b) (4)	26 Jan 2021 15:15:20

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:38
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '3'	Jiamin Li (b) (4)	26 Jan 2021 15:15:20

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:38
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'mg (mg)'	Jiamin Li (b) (4)	26 Jan 2021 15:15:20

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:38
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:15:20

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:38
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'once daily (QD)'	Jiamin Li (b) (4)	26 Jan 2021 15:15:20

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:38
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:15:20

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:38
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	26 Jan 2021 15:15:20

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:38
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 15:15:20

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:38
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '09 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:15:20

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:17:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:38
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 15:15:20

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:38
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:15:20

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:38
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '09 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 15:15:20

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:38
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 15:15:20

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:38
User entered '1'	System	26 Jan 2021 15:15:20

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:38
User entered '1'	System	26 Jan 2021 15:15:20

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:38
User entered '804 (804)'	System	26 Jan 2021 15:15:20

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:17:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:18
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 17:17:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 17:17:52
Data point term sent to Coder User entered 'Tylenol'	System Jiamin Li (b) (4)	26 Jan 2021 17:17:11 26 Jan 2021 17:16:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:18
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:18
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'COVID-19'	Jiamin Li (b) (4)	26 Jan 2021 17:16:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:18
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '500'	Jiamin Li (b) (4)	26 Jan 2021 17:16:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:18
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'mg (mg)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:18
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 17:16:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:18
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'once daily (QD)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:18
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 17:16:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:18
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:18
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 17:16:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:18
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '19 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 17:16:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:17:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:18
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	26 Jan 2021 17:16:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:18
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 17:17:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Jan 2021 17:17:00
User entered 'No (N)' reason for change: Data Entry Error	Jiamin Li (b) (4)	26 Jan 2021 17:17:00
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Jan 2021 17:16:56
User entered empty.	Jiamin Li (b) (4)	26 Jan 2021 17:16:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:18
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '19 Jan 2021'	Jiamin Li (b) (4)	26 Jan 2021 17:16:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:18
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	26 Jan 2021 17:16:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:18
User entered '1'	System	26 Jan 2021 17:16:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:18
User entered '1'	System	26 Jan 2021 17:16:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:18
User entered '804 (804)'	System	26 Jan 2021 17:16:56

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:17:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:14
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 17:46:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 17:46:48
Data point term sent to Coder User entered 'Dexamethasone'	System Jiamin Li (b) (4)	12 Mar 2021 17:45:15 12 Mar 2021 17:44:44

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:14
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	12 Mar 2021 17:44:44

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:14
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'COVID-19'	Jiamin Li (b) (4)	12 Mar 2021 17:44:44

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:14
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '6'	Jiamin Li (b) (4)	12 Mar 2021 17:44:44

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:14
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'mg (mg)'	Jiamin Li (b) (4)	12 Mar 2021 17:44:44

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:14
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	12 Mar 2021 17:44:44

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:14
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'once daily (QD)'	Jiamin Li (b) (4)	12 Mar 2021 17:44:44

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:14
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	12 Mar 2021 17:44:44

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:14
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	12 Mar 2021 17:44:44

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:14
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	12 Mar 2021 17:44:44

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:14
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '06 Jan 2021'	Jiamin Li (b) (4)	12 Mar 2021 17:44:44

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:17:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:14
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	12 Mar 2021 17:44:44

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:14
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	12 Mar 2021 17:44:44

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:14
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '15 Jan 2021'	Jiamin Li (b) (4)	12 Mar 2021 17:44:44

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:14
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	12 Mar 2021 17:44:44

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:14
User entered '1'	System	12 Mar 2021 17:44:44

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:14
User entered '1'	System	12 Mar 2021 17:44:44

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:14
User entered '804 (804)'	System	12 Mar 2021 17:44:44

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:17:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENNA [SENNOSIDE A+B] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 09:16:29
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 Mar 2021 09:16:29
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Data point term sent to Coder	System	12 Mar 2021 17:45:15
User entered 'Senna'	Jiamin Li (b) (4) (b) (4)	12 Mar 2021 17:45:12

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:17:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:11
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	12 Mar 2021 17:45:12

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:11
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'COVID-19'	Jiamin Li (b) (4)	12 Mar 2021 17:45:12

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:17:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:11
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '17.2'	Jiamin Li (b) (4)	12 Mar 2021 17:45:12

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:17:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:11
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'mg (mg)'	Jiamin Li (b) (4)	12 Mar 2021 17:45:12

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:17:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:11
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	12 Mar 2021 17:45:12

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:17:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:11
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'once daily (QD)'	Jiamin Li (b) (4)	12 Mar 2021 17:45:12

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:17:27

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:11
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	12 Mar 2021 17:45:12

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:17:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:11
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Oral (ORAL)'	Jiamin Li (b) (4)	12 Mar 2021 17:45:12

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:17:27

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:11
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	12 Mar 2021 17:45:12

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:17:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:11
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '05 Jan 2021'	Jiamin Li (b) (4)	12 Mar 2021 17:45:12

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:17:27

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:11
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '0'	Jiamin Li (b) (4)	12 Mar 2021 17:45:12

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:17:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:11
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	12 Mar 2021 17:45:12

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:17:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:11
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '11 Jan 2021'	Jiamin Li (b) (4)	12 Mar 2021 17:45:12

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:17:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:11
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'No (N)'	Jiamin Li (b) (4)	12 Mar 2021 17:45:12

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:17:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:11
User entered '1'	System	12 Mar 2021 17:45:12

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:11
User entered '1'	System	12 Mar 2021 17:45:12

US3702010

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:17:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:21:11
User entered '804 (804)'	System	12 Mar 2021 17:45:12

US3702010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:17:27

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Jiamin Li (b) (4)	06 Apr 2021 18:03:03
User entered 'No (N)'	Jiamin Li (b) (4)	17 Mar 2021 19:15:34

US3702010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:17:27

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
User entered '20 Jan 2021'	Jiamin Li (b) (4)	06 Apr 2021 18:03:38

US3702010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:17:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
User entered 'Hi-flow oxygen and bi-level non-invasive positive pressure ventilation'	Jiamin Li (b) (4)	06 Apr 2021 18:03:38

US3702010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
User entered 'Adverse Event (AE)'	Jiamin Li (b) (4)	06 Apr 2021 18:03:38

US3702010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:17:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
User entered empty.	Jiamin Li (b) (4)	06 Apr 2021 18:03:38

US3702010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:17:27

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
User entered '24 Jan 2021'	Jiamin Li (b) (4)	06 Apr 2021 18:03:53

US3702010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:17:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
User entered 'Intubation'	Jiamin Li (b) (4)	06 Apr 2021 18:03:53

US3702010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
User entered 'Adverse Event (AE)'	Jiamin Li (b) (4)	06 Apr 2021 18:03:53

US3702010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:17:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:04
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
User entered empty.	Jiamin Li (b) (4)	06 Apr 2021 18:03:53

US3702010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:17:27

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:09
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
User entered '12 Feb 2021'	Jiamin Li (b) (4)	21 Apr 2021 18:44:28

US3702010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:17:27

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:09
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
User entered 'Cardioversion'	Jiamin Li (b) (4)	21 Apr 2021 18:44:28

US3702010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:17:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:09
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
User entered 'Adverse Event (AE)'	Jiamin Li (b) (4)	21 Apr 2021 18:44:28

US3702010

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:17:27

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:23:09
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
User entered empty.	Jiamin Li (b) (4)	21 Apr 2021 18:44:28

US3702010

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:17:27

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:02:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '02 Oct 2020'	Jiamin Li (b) (4)	15 Jan 2021 16:08:35

US3702010

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:17:27

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:02:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Other (OTHER)' reason for change: Data Entry Error	Jiamin Li (b) (4)	15 Jan 2021 16:11:32
User entered 'Due to SARS-COV-2 (COVID)'	Jiamin Li (b) (4)	15 Jan 2021 16:08:35

US3702010

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:02:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Participant refused second injection due to side effects. He consented to continue study visits.' reason for change: Data Entry Error	Jiamin Li (b) (4)	15 Jan 2021 16:11:32
User entered empty.	Jiamin Li (b) (4)	15 Jan 2021 16:08:35

US3702010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:17:27

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:02:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '25 Feb 2021'	Jiamin Li (b) (4)	12 Mar 2021 17:46:04

US3702010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:17:27

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:02:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Death (DEATH)'	Jiamin Li (b) (4)	12 Mar 2021 17:46:04

US3702010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:02:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	12 Mar 2021 17:46:04

US3702010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:17:27

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:02:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Adverse event (ADVERSE EVENT)'	Jiamin Li (b) (4)	12 Mar 2021 17:46:04

US3702010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:17:27

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:02:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered empty.	Jiamin Li (b) (4)	12 Mar 2021 17:46:04

US3702010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:17:27

Date of death (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:02:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '25 Feb 2021'	Jiamin Li (b) (4)	12 Mar 2021 17:46:04

US3702010

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:17:27

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:02:34
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'Unknown (UNK)'	Jiamin Li (b) (4)	12 Mar 2021 17:46:04

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'USA-US133-2021-MRNA-1273-P301000001'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:38:08
Un-reviewed for Safety.	System	06 Apr 2021 17:57:51
Signature has been broken.	System	06 Apr 2021 17:57:51
User entered 'Yes (Y)'	System	06 Apr 2021 17:57:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Kristen'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Marks'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '525 East 68th Street'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'New York'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'NY'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '10065'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'US'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '9'	System	23 Apr 2021 12:27:21
User entered '8'	System	14 Apr 2021 14:27:04
User entered '7'	System	12 Apr 2021 17:38:22
User entered '6'	System	07 Apr 2021 14:11:18
User entered '5'	System	15 Mar 2021 15:59:42
User entered '4'	System	17 Feb 2021 16:10:54
User entered '3'	System	02 Feb 2021 15:17:45
User entered '2'	System	28 Jan 2021 19:35:58
User entered '1'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'USA-US133-2021-MRNA-1273-P301000001'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:38:08
Un-reviewed for Safety.	System	06 Apr 2021 17:57:51
Signature has been broken.	System	06 Apr 2021 17:57:51
User entered 'Yes (Y)'	System	06 Apr 2021 17:57:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Kristen'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Marks'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '525 East 68th Street'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'New York'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'NY'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '10065'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'US'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '9'	System	23 Apr 2021 12:27:21
User entered '8'	System	14 Apr 2021 14:27:04
User entered '7'	System	12 Apr 2021 17:38:22
User entered '6'	System	07 Apr 2021 14:11:18
User entered '5'	System	15 Mar 2021 15:59:42
User entered '4'	System	17 Feb 2021 16:10:54
User entered '3'	System	02 Feb 2021 15:17:45
User entered '2'	System	28 Jan 2021 19:35:58
User entered '1'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:17:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '12/Jan/2021 10:25'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'I'	(b) (4), (b) (6)	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'USA-US133-2021-MRNA-1273-P301000001'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:38:08
Un-reviewed for Safety.	System	06 Apr 2021 17:57:51
Signature has been broken.	System	06 Apr 2021 17:57:51
User entered 'Yes (Y)'	System	06 Apr 2021 17:57:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Kristen'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Marks'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '525 East 68th Street'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'New York'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'NY'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '10065'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'US'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '9'	System	23 Apr 2021 12:27:21
User entered '8'	System	14 Apr 2021 14:27:04
User entered '7'	System	12 Apr 2021 17:38:22
User entered '6'	System	07 Apr 2021 14:11:18
User entered '5'	System	15 Mar 2021 15:59:42
User entered '4'	System	17 Feb 2021 16:10:54
User entered '3'	System	02 Feb 2021 15:17:45
User entered '2'	System	28 Jan 2021 19:35:58
User entered '1'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:17:27

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '28/Jan/2021 19:35'	System	28 Jan 2021 19:35:58

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 15:17:29
User entered 'I'	(b) (4), (b) (6)	28 Jan 2021 19:35:58

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'USA-US133-2021-MRNA-1273-P301000001'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:38:08
Un-reviewed for Safety.	System	06 Apr 2021 17:57:51
Signature has been broken.	System	06 Apr 2021 17:57:51
User entered 'Yes (Y)'	System	06 Apr 2021 17:57:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Kristen'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Marks'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '525 East 68th Street'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'New York'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'NY'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '10065'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'US'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '9'	System	23 Apr 2021 12:27:21
User entered '8'	System	14 Apr 2021 14:27:04
User entered '7'	System	12 Apr 2021 17:38:22
User entered '6'	System	07 Apr 2021 14:11:18
User entered '5'	System	15 Mar 2021 15:59:42
User entered '4'	System	17 Feb 2021 16:10:54
User entered '3'	System	02 Feb 2021 15:17:45
User entered '2'	System	28 Jan 2021 19:35:58
User entered '1'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:17:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '02/Feb/2021 10:17'	System	02 Feb 2021 15:17:45

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:10:59
User entered 'I'	(b) (4), (b) (6)	02 Feb 2021 15:17:45

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'USA-US133-2021-MRNA-1273-P301000001'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:38:08
Un-reviewed for Safety.	System	06 Apr 2021 17:57:51
Signature has been broken.	System	06 Apr 2021 17:57:51
User entered 'Yes (Y)'	System	06 Apr 2021 17:57:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Kristen'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Marks'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '525 East 68th Street'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'New York'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'NY'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '10065'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'US'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '9'	System	23 Apr 2021 12:27:21
User entered '8'	System	14 Apr 2021 14:27:04
User entered '7'	System	12 Apr 2021 17:38:22
User entered '6'	System	07 Apr 2021 14:11:18
User entered '5'	System	15 Mar 2021 15:59:42
User entered '4'	System	17 Feb 2021 16:10:54
User entered '3'	System	02 Feb 2021 15:17:45
User entered '2'	System	28 Jan 2021 19:35:58
User entered '1'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:17:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '17/Feb/2021 11:10'	System	17 Feb 2021 16:10:54

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:10:59
User entered 'I'	(b) (4), (b) (6)	17 Feb 2021 16:10:54

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'USA-US133-2021-MRNA-1273-P301000001'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:38:08
Un-reviewed for Safety.	System	06 Apr 2021 17:57:51
Signature has been broken.	System	06 Apr 2021 17:57:51
User entered 'Yes (Y)'	System	06 Apr 2021 17:57:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Kristen'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Marks'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '525 East 68th Street'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'New York'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'NY'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '10065'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'US'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '9'	System	23 Apr 2021 12:27:21
User entered '8'	System	14 Apr 2021 14:27:04
User entered '7'	System	12 Apr 2021 17:38:22
User entered '6'	System	07 Apr 2021 14:11:18
User entered '5'	System	15 Mar 2021 15:59:42
User entered '4'	System	17 Feb 2021 16:10:54
User entered '3'	System	02 Feb 2021 15:17:45
User entered '2'	System	28 Jan 2021 19:35:58
User entered '1'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:17:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered '15/Mar/2021 11:59'	System	15 Mar 2021 15:59:42

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:38:08
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
User entered 'I'	(b) (4), (b) (6)	15 Mar 2021 15:59:42

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'USA-US133-2021-MRNA-1273-P301000001'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:38:08
Un-reviewed for Safety.	System	06 Apr 2021 17:57:51
Signature has been broken.	System	06 Apr 2021 17:57:51
User entered 'Yes (Y)'	System	06 Apr 2021 17:57:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Kristen'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Marks'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '525 East 68th Street'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'New York'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'NY'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '10065'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'US'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '9'	System	23 Apr 2021 12:27:21
User entered '8'	System	14 Apr 2021 14:27:04
User entered '7'	System	12 Apr 2021 17:38:22
User entered '6'	System	07 Apr 2021 14:11:18
User entered '5'	System	15 Mar 2021 15:59:42
User entered '4'	System	17 Feb 2021 16:10:54
User entered '3'	System	02 Feb 2021 15:17:45
User entered '2'	System	28 Jan 2021 19:35:58
User entered '1'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:17:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User entered '07/Apr/2021 07:11'	System	07 Apr 2021 14:11:18

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:38:08
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 14:11:18

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'USA-US133-2021-MRNA-1273-P301000001'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:38:08
Un-reviewed for Safety.	System	06 Apr 2021 17:57:51
Signature has been broken.	System	06 Apr 2021 17:57:51
User entered 'Yes (Y)'	System	06 Apr 2021 17:57:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Kristen'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Marks'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '525 East 68th Street'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'New York'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'NY'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '10065'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'US'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '9'	System	23 Apr 2021 12:27:21
User entered '8'	System	14 Apr 2021 14:27:04
User entered '7'	System	12 Apr 2021 17:38:22
User entered '6'	System	07 Apr 2021 14:11:18
User entered '5'	System	15 Mar 2021 15:59:42
User entered '4'	System	17 Feb 2021 16:10:54
User entered '3'	System	02 Feb 2021 15:17:45
User entered '2'	System	28 Jan 2021 19:35:58
User entered '1'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:17:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User entered '12/Apr/2021 13:38'	System	12 Apr 2021 17:38:22

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 14:28:06
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 17:38:22

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'USA-US133-2021-MRNA-1273-P301000001'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:38:08
Un-reviewed for Safety.	System	06 Apr 2021 17:57:51
Signature has been broken.	System	06 Apr 2021 17:57:51
User entered 'Yes (Y)'	System	06 Apr 2021 17:57:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Kristen'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Marks'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '525 East 68th Street'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'New York'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'NY'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '10065'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'US'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '9'	System	23 Apr 2021 12:27:21
User entered '8'	System	14 Apr 2021 14:27:04
User entered '7'	System	12 Apr 2021 17:38:22
User entered '6'	System	07 Apr 2021 14:11:18
User entered '5'	System	15 Mar 2021 15:59:42
User entered '4'	System	17 Feb 2021 16:10:54
User entered '3'	System	02 Feb 2021 15:17:45
User entered '2'	System	28 Jan 2021 19:35:58
User entered '1'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:17:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User entered '14/Apr/2021 10:27'	System	14 Apr 2021 14:27:04

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 14:28:06
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 14:27:04

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'USA-US133-2021-MRNA-1273-P301000001'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	16 Apr 2021 13:11:29
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:38:08
Un-reviewed for Safety.	System	06 Apr 2021 17:57:51
Signature has been broken.	System	06 Apr 2021 17:57:51
User entered 'Yes (Y)'	System	06 Apr 2021 17:57:51
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	28 Jan 2021 19:35:01
Un-reviewed for Safety.	System	27 Jan 2021 21:16:44
User entered 'Yes (Y)'	System	27 Jan 2021 21:16:44
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'No (N)'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Kristen'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'Marks'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '525 East 68th Street'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'New York'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'NY'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered '10065'	System	12 Jan 2021 15:25:00

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:01:21
User signature succeeded.	Kristen Marks (b) (4)	15 Mar 2021 20:15:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 15:25:19
User entered 'US'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:17:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User entered '9'	System	23 Apr 2021 12:27:21
User entered '8'	System	14 Apr 2021 14:27:04
User entered '7'	System	12 Apr 2021 17:38:22
User entered '6'	System	07 Apr 2021 14:11:18
User entered '5'	System	15 Mar 2021 15:59:42
User entered '4'	System	17 Feb 2021 16:10:54
User entered '3'	System	02 Feb 2021 15:17:45
User entered '2'	System	28 Jan 2021 19:35:58
User entered '1'	System	12 Jan 2021 15:25:12

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:17:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 20:15:35
User entered '23/Apr/2021 08:27'	System	23 Apr 2021 12:27:21

US3702010

Folder: SAE USA-US133-2021-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:17:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:35:50
User signature succeeded.	Kristen Marks (b) (4)	29 Apr 2021 15:29:06
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 20:15:37
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 12:27:29
User entered 'I'	(b) (4), (b) (6)	23 Apr 2021 12:27:21