

US3162006 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:24:55

All time stamps listed in this document are displayed in GMT

US3162006

Form: Participant Creation

Data signed: (b) (4) 12 Feb 2021 21:07:11

Generated On: 09 Jun 2021 15:24:55

Participant ID

US3162006

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

US3162006

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

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

Visit date (dd MMM yyyy)	27 JUL 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
------------	------

US3162006

Folder: Screening

Form: Demographics

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	75
Age Units	YEARS
Age (Derived)	75
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3162006

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Date of Informed Consent (*dd MMM yyyy*) 27 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

US3162006

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3162006

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Were any significant conditions reported?

Yes ☒
No ☐

US3162006

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3162006

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3162006

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Condition	RESTLESS LEG SYNDROME, BILATERAL
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

US3162006

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Condition	OSTEOPOROSIS
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3162006

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

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

US3162006

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Condition	GASTRITIS
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3162006

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Condition	NATURAL MENOPASUAL
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3162006

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Condition	INTERMITTENT ESOPHAGEAL SPASM
Start date (dd MMM yyyy)	UN 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)	_____

US3162006

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	27 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	16:56 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 16:56
Height (<i>xxx.x</i>)	61 in
Weight (<i>xxx.x</i>)	138.2 lb
BMI (<i>xxx.x</i>)	26.16726 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162006

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 JUL 2020

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

US3162006

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Date of assessment (*dd MMM yyyy*) 27 JUL 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2004

Date of last menstruation unknown False

US3162006

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

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 NONE

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3162006

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

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

US3162006

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

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

Visit date (dd MMM yyyy)	27 JUL 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
------------	--------

US3162006

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

What was the date of randomization? (dd MMM yyyy) 27 JUL 2020

What was the participant's randomization number? 184042

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 ☒

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

Height	ND - Not Done
Weight	ND - Not Done

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 JUL 2020
Time of assessment (00:00-23:59)	16:56 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 16:56
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	27 JUL 2020
Time of assessment (00:00-23:59)	18:38 (24 HR)
Vital Signs Date and Time (derived)	27 JUL 2020 18:38
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3162006

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

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.

US3162006

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

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) 27 JUL 2020

What was the treatment time? (00:00-23:59) 18:00 (24 HR)

Treatment Date and Time (derived) 27 JUL 2020 18:00

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

US3162006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 JUL 2020
Collection time (00:00-23:59)	17:50 (24 HR)
Collection date and time (derived)	27 JUL 2020 17:50

US3162006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Collection date (dd MMM yyyy)			27 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:56	27 JUL 2020 17:56
Nasopharyngeal Swab 2	No		

US3162006

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

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

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

27 JUL 2020 18:20

PC Close Date & Time

27 JUL 2020 20:50

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

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 97.4 °F

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

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

PC Time Stamp	27 JUL 2020 18:44
PC Open Date & Time	27 JUL 2020 09:45
PC Close Date & Time	28 JUL 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

28 JUL 2020 12:00

PC Close Date & Time

29 JUL 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

29 JUL 2020 18:12

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

01 AUG 2020 10:07

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:24:55

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

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:24:55

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

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

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 ☐

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

27 JUL 2020 18:20

PC Close Date & Time

27 JUL 2020 20:50

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 JUL 2020 18:45

PC Open Date & Time

27 JUL 2020 09:45

PC Close Date & Time

28 JUL 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 JUL 2020 12:00

PC Close Date & Time

29 JUL 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 JUL 2020 18:15

PC Open Date & Time

29 JUL 2020 12:00

PC Close Date & Time

30 JUL 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

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 ☐

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

27 JUL 2020 18:20

PC Close Date & Time

27 JUL 2020 20:50

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

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 ☐

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

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

No ☒

Yes ☐

PC Time stamp	27 JUL 2020 18:46
PC Open Date & Time	27 JUL 2020 09:45
PC Close Date & Time	28 JUL 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

50 of 3607

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

Yes ☐

PC Time stamp

PC Open Date & Time

28 JUL 2020 12:00

PC Close Date & Time

29 JUL 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

52 of 3607

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

Yes <input type="checkbox"/>	
PC Time stamp	29 JUL 2020 22:28
PC Open Date & Time	29 JUL 2020 12:00
PC Close Date & Time	30 JUL 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

54 of 3607

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

Yes ☐

PC Time stamp

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 3607

EAB) (1725)

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 10:08
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

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 ☐

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

Yes ☐

PC Time stamp

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

60 of 3607

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

Yes ☐

PC Time stamp

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3162006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3162006

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3162006

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3162006

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

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

Visit date (dd MMM yyyy)	24 AUG 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
------------	--------

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	16:13 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 16:13
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	17:39 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 17:39
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3162006

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

US3162006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

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) 24 AUG 2020

What was the treatment time? (00:00-23:59) 17:02 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 17:02

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

US3162006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 AUG 2020
Collection time (00:00-23:59)	16:50 (24 HR)
Collection date and time (derived)	24 AUG 2020 16:50

US3162006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:56	24 AUG 2020 16:56
Nasopharyngeal Swab 2	No		

US3162006

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 17:25

PC Open Date & Time

24 AUG 2020 17:22

PC Close Date & Time

24 AUG 2020 19:52

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	24 AUG 2020 22:03
PC Open Date & Time	24 AUG 2020 20:47
PC Close Date & Time	25 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 20:13

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 18:09

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 21:44

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 19:52

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 21:01

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

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

24 AUG 2020 17:28

PC Open Date & Time

24 AUG 2020 17:22

PC Close Date & Time

24 AUG 2020 19:52

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 22:07

PC Open Date & Time

24 AUG 2020 20:47

PC Close Date & Time

25 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 20:14

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 18:10

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 21:45

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

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 ☐

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 17:29
PC Open Date & Time	24 AUG 2020 17:22
PC Close Date & Time	24 AUG 2020 19:52

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

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 ☐

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 22:04
PC Open Date & Time	24 AUG 2020 20:47
PC Close Date & Time	25 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

96 of 3607

EAB) (1725)

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 20:15
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

98 of 3607

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

Yes ☐

PC Time stamp

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 3607

EAB) (1725)

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 18:11
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

102 of 3607

EAB) (1725)

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 21:45
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

104 of 3607

EAB) (1725)

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

Yes ☐

PC Time stamp

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

106 of 3607

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

Yes ☐

PC Time stamp

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3162006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3162006

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3162006

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3162006

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3162006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	16:33 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 16:33
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	64 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162006

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

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.

US3162006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	21 SEP 2020
-------------------------------	-------------

Collection time (00:00-23:59)	16:36 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	21 SEP 2020 16:36
------------------------------------	-------------------

US3162006

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:07:15

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 SEP 2020 13:11:30
Patient Cloud Open Date & Time	26 SEP 2020 00:01
Patient Cloud Close Date & Time	30 SEP 2020 23:59

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 OCT 2020 15:00:25

Patient Cloud Open Date & Time

03 OCT 2020 00:01

Patient Cloud Close Date & Time

07 OCT 2020 23:59

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 OCT 2020 15:17:30

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 14:20:13

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 NOV 2020 17:03:57
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	09 NOV 2020 13:43:18
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 113
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	True
Nausea	True
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	29 NOV 2020 12:12:30
Patient Cloud Open Date & Time	25 NOV 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	129 of 3607

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

Date and time of submission

10 DEC 2020 14:58:15

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 07:07:54

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 07:34:27

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 06:00:22
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 10:49:44

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 14:27:31

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 FEB 2021 17:20:05
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 16:57:46
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 18:40:09

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	06 MAR 2021 02:56:52
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	12 MAR 2021 15:10:59
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	17 MAR 2021 18:13:40
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 11:28:42

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 250

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 08:08:53

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 15:37:32

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 278

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 10:13:22

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	23 JUN 2021 00:01
Patient Cloud Close Date & Time	27 JUN 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 341

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	11 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	15 AUG 2021 23:59
---	-------------------

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2021 00:01
Patient Cloud Close Date & Time	29 AUG 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	08 SEP 2021 00:01
Patient Cloud Close Date & Time	12 SEP 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	20 OCT 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	24 OCT 2021 23:59
---	-------------------

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 495

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

Patient Cloud Open Date & Time	23 FEB 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	27 FEB 2022 23:59
---	-------------------

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	13 APR 2022 00:01
Patient Cloud Close Date & Time	17 APR 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	08 JUN 2022 00:01
Patient Cloud Close Date & Time	12 JUN 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	29 JUN 2022 00:01
Patient Cloud Close Date & Time	03 JUL 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 712

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	27 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	10 AUG 2022 00:01
Patient Cloud Close Date & Time	14 AUG 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

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

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3162006

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:24:55

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 18:41:53

US3162006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

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

US3162006

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Was Contact Attempted? Yes ☐
No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

SUBJECT IN CONVALESCENT
PHASE

If Contact Not Made, please provide Comments

US3162006

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3162006

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162006

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3162006

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162006

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	15 FEB 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
------------	--------

US3162006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

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) _____

US3162006

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

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.

US3162006

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	15 FEB 2021
-------------------------------	-------------

Collection time (00:00-23:59)	15:41 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	15 FEB 2021 15:41
------------------------------------	-------------------

US3162006

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162006

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 MAR 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3162006

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162006

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

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

US3162006

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Date of Contact	10 NOV 2020
Time of Contact	11:17
Date and Time of Contact (derived)	10 NOV 2020 11:17
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	9 NOV 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

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 type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

327 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

328 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	10 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	96.3 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

331 of 3607

EAB) (1725)

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

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"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
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 type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

335 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
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 type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

339 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	13 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.1 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input checked="" type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

343 of 3607

EAB) (1725)

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

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"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	14 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.2 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

347 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

348 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

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"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	15 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	93 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.4 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

351 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

352 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

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"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	16 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	96.5 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

355 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

356 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

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"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	17 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.5 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

359 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

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"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	18 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.0 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

363 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	19 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	97.9 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

367 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

368 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

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"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	20 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.1 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

371 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	21 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	97.9 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

375 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

376 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	22 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	94 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.7 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

379 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	23 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.5 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

383 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

387 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

388 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

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"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	25 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.0 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

391 of 3607

EAB) (1725)

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	26 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.6 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

395 of 3607

EAB) (1725)

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	27 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.8 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

399 of 3607

EAB) (1725)

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

400 of 3607

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Date of Visit	10 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	10 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 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 15 NOV 2020

End Date 16 NOV 2020

Oxygen Saturation 93 %

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes ☐
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐
No ☐

Start Date

End Date

ECMO? Yes ☐
No ☐

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☒
No ☐

Start Date

10 NOV 2020

End Date

03 FEB 2021

Evidence of Shock Requires Vasopressors Yes ☐
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☒
No ☐

Start Date

11 NOV 2020

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☒
No ☐

Start Date

11 NOV 2020

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

[Generate Next COVID-19 Assessment](#)

Yes ☒
No ☐

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 12 Feb 2021 21:07:13

Generated On: 09 Jun 2021 15:24:55

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	12 NOV 2020
Day 5	Yes	14 NOV 2020
Day 7	Yes	16 NOV 2020
Day 9	Yes	18 NOV 2020
Day 14	Yes	23 NOV 2020
Day 21	Yes	30 NOV 2020
Day 28	Yes	7 DEC 2020

US3162006

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:07:13

Generated On: 09 Jun 2021 15:24:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3162006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:07:13

Generated On: 09 Jun 2021 15:24:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 NOV 2020
Time of assessment (00:00-23:59)	14:01 (24 HR)
Vital Signs Date and Time (derived)	10 NOV 2020 14:01
Temperature (xxx.x)	96.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162006

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:07:13

Generated On: 09 Jun 2021 15:24:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 NOV 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3162006

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 12 Feb 2021 21:07:13

Generated On: 09 Jun 2021 15:24:55

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

10 NOV 2020

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	7 DEC 2020
Time of assessment (<i>00:00-23:59</i>)	14:48 (24 HR)
Vital Signs Date and Time (derived)	7 DEC 2020 14:48
Temperature (<i>xxx.x</i>)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	57 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 DEC 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

7 DEC 2020

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 21:07:13

Generated On: 09 Jun 2021 15:24:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	3 FEB 2021
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Date of updated informed consent (<i>dd MMM yyyy</i>)	3 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	3 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 21:07:13

Generated On: 09 Jun 2021 15:24:55

Height	61 in
Weight	138.2 lb
BMI (xxx.x)	26.16726

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 21:07:13

Generated On: 09 Jun 2021 15:24:55

Height	61 in
Weight	138.2 lb
BMI (xxx.x)	26.16726
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 FEB 2021
Time of assessment (00:00-23:59)	15:30 (24 HR)
Vital Signs Date and Time (derived)	3 FEB 2021 15:30
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 21:07:13

Generated On: 09 Jun 2021 15:24:55

Height	61 in
Weight	138.2 lb
BMI (xxx.x)	26.16726
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 FEB 2021
Time of assessment (00:00-23:59)	16:30 (24 HR)
Vital Signs Date and Time (derived)	3 FEB 2021 16:30
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 21:07:13

Generated On: 09 Jun 2021 15:24:55

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.

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 21:07:13

Generated On: 09 Jun 2021 15:24:55

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 3 FEB 2021

What was the treatment time? (00:00-23:59) 15:55 (24 HR)

Treatment Date and Time (derived) 3 FEB 2021 15:55

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

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 21:07:13

Generated On: 09 Jun 2021 15:24:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	3 FEB 2021
-------------------------------	------------

Collection time (00:00-23:59)	15:40 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	3 FEB 2021 15:40
------------------------------------	------------------

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Feb 2021 21:07:13

Generated On: 09 Jun 2021 15:24:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 FEB 2021
Collection time (00:00 - 23:59)	15:43
Collection Date and Time (derived)	3 FEB 2021 15:43

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:07:13

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162006

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 FEB 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3162006

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3162006

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	11 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
------------	-------

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 MAR 2021
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 10:15
Temperature (xxx.x)	96.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" 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	

US3162006

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

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.

US3162006

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify _____

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 MAR 2021

What was the treatment time? (00:00-23:59) 11:34 (24 HR)

Treatment Date and Time (derived) 11 MAR 2021 11:34

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

US3162006

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162006

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 MAR 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3162006

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162006

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	8 APR 2021
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD57
------------	-------

US3162006

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

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) _____

US3162006

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

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.

US3162006

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 16:53:19

Generated On: 09 Jun 2021 15:24:55

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	8 APR 2021
-------------------------------	------------

Collection time (00:00-23:59)	10:12 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	8 APR 2021 10:12
------------------------------------	------------------

US3162006

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Feb 2021 21:07:11

Generated On: 09 Jun 2021 15:24:55

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

AEID	USA-US074-2020-MRNA-1273-P30 1000008
Adverse event	SYMPTOMATIC COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	9 NOV 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)	27 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

441 of 3607

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

SUBJECT HAD ONSET OF COVID SYMPTOMS ON 9NOV20, HAD ILLNESS VISIT ON 10NOV20, WAS ADMITTED TO HOSPITAL ON 11NOV20 AFTER ER VISIT SHOWING COVID AND ACUTE RENAL FAILURE. THE RENAL FAILURE WAS THOUGHT TO BE DUE IN LARGE PART TO HER TAKING HYDROCHLOROTHIAZIDE, AND THIS MEDICATION WAS STOPPED. SHE WAS NOT ON OXYGEN DURING HER OVERNIGHT HOSPITALIZATION, AND SHE WAS TREATED WITH HYDRATION BUT NO MEDICATIONS SPECIFICALLY FOR COVID. AFTER DISCHARGE, SHE HAD AN UNEVENTFUL COURSE, HAD ONE TELEMEDICINE VISIT WITH HER PCP AND FULLY RECOVERED.,

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

AEID	USA-US074-2020-MRNA-1273-P30 1000008
Adverse event	ACUTE RENAL FAILURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 NOV 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)	12 NOV 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 type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	11 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	12 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

444 of 3607

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

SUBJECT HAD ONSET OF COVID SYMPTOMS ON 09NOV20 AND WAS SEEN FOR ILLNESS VISIT ON 10NOV20. ON 11NOV20, AT 1000, SHE WAS LIGHTHEADED AND TOO WEAK TO STAND UP, AND WAS TAKEN TO HOSPITAL ER. COVID PCR TEST WAS POSITIVE THERE, AND SHE WAS FOUND TO HAVE ACUTE RENAL FAILURE WITH BUN 37 AND CREATININE 2.2. SHE WAS ADMITTED DUE TO THAT DIAGNOSIS. WE LEARNED OF HER ADMISSION ON 12NOV20, AND SHE WAS DISCHARGED THAT DAY. (12NOV2020).
ADDENDUM ON 13NOV2020: RECEIVED MEDICAL RECORDS SHOWING THAT ADMITTING DIAGNOSIS WAS ACUTE RENAL FAILURE. DISCHARGE DIAGNOSES INDICATE "ASYMPTOMATIC COVID" BUT SUBJECT HAD A BAD COUGH AND WAS TREATED WITH ZITHROMAX, DEXAMETHASONE AND ROCEPHIN, SO THAT DIAGNOSIS SHOULD BE SYMPTOMATIC COVID-19. SHE ALSO HAD HYPONATREMIA (129) WHICH RESOLVED AFTER HYDRATION WITH NORMAL SALINE. SHE NEVER NEEDED

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

OXYGEN (ALL O2 SATURATIONS WERE 93 OR GREATER), AND HER TWO CHEST XRAYs WERE NORMAL. HER PHYSICIAN ATTRIBUTED HER RENAL FAILURE TO HYDROCHLOROTHIAZIDE AND CONFERRED WITH HER PCP, THEN STOPPED THAT MEDICATION. THE FOLLOWING DAY, HER CREATININE WAS 1.2 AND BUN 27.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

AEID

Adverse event

FALL IN PARKING LOT

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)

10 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

448 of 3607

EAB) (1725)

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

AEID	
Adverse event	HYPONATREMIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 NOV 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)	12 NOV 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	

PRODUCTION RELEASE (v12.003
EAB) (1725)

450 of 3607

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

AEID

Adverse event

LIGHTHEADEDNESS

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)

10 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

452 of 3607

EAB) (1725)

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

SUBJECT COMPLAINED OF
FEELING "WOOZY" ON 10NOV20
WITH WORSENING ON
11NOV20. WAS TREATED WITH
MECLIZINE IN ER ON 11NOV20
AND IT SUBSEQUENTLY
RESOLVED. ON 14NOV20,
SUBJECT STATED SHE NEVER
HAD VERTIGO, JUST
LIGHTHEADEDNESS, SO TERM
WAS UPDATED. HOSPITAL
RECORDS RECEIVED 13NOV20
STATE SHE NEVER LOST
CONSCIOUSNESS, SO TERM
UPDATED TO
LIGHTHEADEDNESS

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

AEID

Adverse event

LIGHTHEADEDNESS

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)

19 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

455 of 3607

EAB) (1725)

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

AEID	
Adverse event	WORSENING OF GASTRITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

457 of 3607

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

AEID	
Adverse event	WORSENING OF HYPERTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	03 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

459 of 3607

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input checked="" type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

AEID	
Adverse event	INTERMITTENT BILATERAL FINGER NUMBNESS
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Start date (dd MMM yyyy)	15 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
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="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

464 of 3607

EAB) (1725)

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN SEP 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	11 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication LOSARTAN POTASSIUM

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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

466 of 3607

EAB) (1725)

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN OCT 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 6.25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

468 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

470 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication RESTLESS LEG SYNDROME

Dose per administration 300

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☒
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

472 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1990	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication ROPINIROLE

Prophylaxis Yes ☐
No ☒

Indication RESTLESS LEG SYNDROME

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

EAB) (1725)

474 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication VENLAFAXINE

Prophylaxis Yes ☐
No ☒

Indication RESTLESS LEG SYNDROME

Dose per administration 37.5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

476 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN APR 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

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)

478 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROTECTION

Dose per administration 81

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

480 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN SEP 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication VIRTUSSIN AC (CODEINE
PHOSPHATE/ GUAIFENESIN)

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 10/100

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

482 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	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)	10 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		10 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 0.5

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

484 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	Intramuscular	<input checked="" 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 type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		8 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 8 OCT 2020		
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"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication SHINGRIX

Prophylaxis Yes ☒
No ☐

Indication SHINGLES PREVENTION

Dose per administration 0.5

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

486 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	Intramuscular	<input checked="" 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 type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		8 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 8 OCT 2020		
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"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication ROCEPHIN

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 1000

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)

488 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	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)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC 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

490 of 3607

EAB) (1725)

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication ZITHROMAX

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC 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

492 of 3607

EAB) (1725)

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication NORMAL SALINE

Prophylaxis Yes ☐
No ☒

Indication ACUTE RENAL FAILURE

Dose per administration 1000

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)

494 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication VITAMIN C

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 1000

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

496 of 3607

EAB) (1725)

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication VITAMIN C

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC 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)

498 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	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 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication CHOLECALCIFEROL

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 5000

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

500 of 3607

EAB) (1725)

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication HEPARIN

Prophylaxis Yes ☒
No ☐

Indication CLOT PREVENTION

Dose per administration 5000

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

502 of 3607

EAB) (1725)

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication ZINC SULFATE

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 220

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

504 of 3607

EAB) (1725)

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	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 type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 12 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication THIAMINE

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

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)

506 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	11 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication MECLIZINE

Prophylaxis Yes ☐
No ☒

Indication LIGHTHEADEDNESS

Dose per administration 12.5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

508 of 3607

EAB) (1725)

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTRITIS

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)

510 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC 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

512 of 3607

EAB) (1725)

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	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 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication ZINC/VITAMIN C (GARDEN OF LIFE)

Prophylaxis Yes ☒
No ☐

Indication COVID PREVENTION

Dose per administration 30/60

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

514 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	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)		21 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication TYLENOL EXTRA STRENGTH

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC 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

516 of 3607

EAB) (1725)

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	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 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTRITIS

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)

518 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	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)	04 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication CLONIDINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF
HYPERTENSION

Dose per administration 0.1

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)

520 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	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)	03 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication CAPTOPRIL

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF
HYPERTENSION

Dose per administration 25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

522 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	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)	03 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication TRIAMTERENE/HYDROCHLORO
THIAZIDE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF
HYPERTENSION

Dose per administration 37.5/25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

524 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	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)		04 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Name of Medication TRIAMTERENE/HYDROCHLORO
THIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 37.5/25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

526 of 3607

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

	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)		12 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Feb 2021 21:07:12

Generated On: 09 Jun 2021 15:24:55

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 24 Apr 2021 16:53:18

Generated On: 09 Jun 2021 15:24:55

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
11 NOV 2020	PORTABLE CHEST XRAY	Adverse Event	
12 NOV 2020	SINGLE VIEW CHEST XRAY	Adverse Event	
11 NOV 2020	CT SCAN OF HEAD WITHOUT CONTRAST	Adverse Event	
11 NOV 2020	RENAL ULTRASOUND	Adverse Event	
11 NOV 2020	ELECTROCARDIOGRAM	Adverse Event	

US3162006

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:24:55

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3162006

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:24:55

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

SAEID	USA-US074-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

SAEID	USA-US074-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	13/NOV/2020 10:33
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

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

SAEID	USA-US074-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/NOV/2020 13:40
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

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

SAEID	USA-US074-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/NOV/2020 18:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

SAEID	USA-US074-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	30/NOV/2020 14:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Data signed: (b) (4) 12 Feb 2021 21:07:14

Generated On: 09 Jun 2021 15:24:55

SAEID	USA-US074-2020-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/DEC/2020 10:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3162006 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

US3162006

Form: Participant Creation

Generated On: 09 Jun 2021 15:24:55

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'US3162006'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 00:34:32

US3162006

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:13:13

US3162006

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '27 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 00:34:33

US3162006

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

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 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 14:13:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jul 2020 14:13:19
User entered 'Clinic (Clinic)' reason for change: New Information	Jared Bradshaw (b) (4)	28 Jul 2020 14:13:19
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 14:13:13
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:13:13

US3162006

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered 'SCRN'	System	28 Jul 2020 14:13:13

US3162006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:24:55

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered (b) (6) 1945'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 00:34:34

US3162006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:24:55

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '75'	Jared Bradshaw (b) (4)	28 Jul 2020 14:14:01

US3162006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:24:55

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered 'YEARS'	System	28 Jul 2020 14:14:01

US3162006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:24:55

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered '75'	System	28 Jul 2020 01:15:31

US3162006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:24:55

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Female (F)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:14:01

US3162006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:24:55

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:14:01

US3162006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:24:55

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'I'	Jared Bradshaw (b) (4)	28 Jul 2020 14:14:01

US3162006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:24:55

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:14:01

US3162006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:24:55

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:14:01

US3162006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:24:55

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:14:01

US3162006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:24:55

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:14:01

US3162006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:24:55

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:14:01

US3162006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:24:55

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:14:01

US3162006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:24:55

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:14:01

US3162006

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:24:55

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:14:01

US3162006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:24:55

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 01:15:31

US3162006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:24:55

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered 'Jul 2020'	System	28 Jul 2020 01:15:31

US3162006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:24:55

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered '2020'	System	28 Jul 2020 01:15:31

US3162006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:24:55

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Amendment 1 (1)'	Jared Bradshaw (b) (4)	28 Jul 2020 01:15:31

US3162006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:24:55

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 01:15:31

US3162006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:24:55

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 01:15:31

US3162006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:24:55

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 01:15:31

US3162006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:24:55

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 01:15:31

US3162006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:24:55

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 00:34:33

US3162006

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:24:55

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered 'I'	System	28 Jul 2020 01:15:37

US3162006

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:24:55

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 01:15:37

US3162006

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:24:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:14:25

US3162006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:24:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
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)	28 Jul 2020 14:15:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 14:15:19
Data point term sent to Coder	System	28 Jul 2020 14:14:53
User entered 'Hypertension'	Jared Bradshaw (b) (4)	28 Jul 2020 14:14:45

US3162006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'un UNK 2014'	Jared Bradshaw (b) (4)	28 Jul 2020 14:14:45

US3162006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:14:45

US3162006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:24:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:14:45

US3162006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:24:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:14:45

US3162006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:24:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:14:45

US3162006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:24:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered 'Jan 2014'	System	28 Jul 2020 14:14:45

US3162006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:24:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered '2014'	System	28 Jul 2020 14:14:45

US3162006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:24:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered empty.	System	28 Jul 2020 14:14:45

US3162006

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:24:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered empty.	System	28 Jul 2020 14:14:45

US3162006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:24:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 14:17:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 14:17:23
Data point term sent to Coder	System	28 Jul 2020 14:15:53
User entered 'hyperlipidemia'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:02

US3162006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'un UNK 2014'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:02

US3162006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:02

US3162006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:24:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:02

US3162006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:24:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:02

US3162006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:24:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:02

US3162006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:24:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered 'Jan 2014'	System	28 Jul 2020 14:15:02

US3162006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:24:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered '2014'	System	28 Jul 2020 14:15:02

US3162006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:24:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered empty.	System	28 Jul 2020 14:15:02

US3162006

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:24:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered empty.	System	28 Jul 2020 14:15:02

US3162006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:24:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 23:37:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 23:37:46
User closed query 'Per DM CLR: Please specify the laterality of RESTLESS LEG SYNDROME. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 16:52:24
Data point term sent to Coder	System	14 Sep 2020 18:48:25
Query 'Per DM CLR: Please specify the laterality of RESTLESS LEG SYNDROME. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'UPDATED' (Site from DM).	Judith Kirstein (b) (4)	14 Sep 2020 18:47:56
Coding entries removed.	Judith Kirstein (b) (4)	14 Sep 2020 18:47:43
User entered 'RESTLESS LEG SYNDROME, BILATERAL' reason for change: Data Entry Error	Judith Kirstein (b) (4)	14 Sep 2020 18:47:43
User opened query 'Per DM CLR: Please specify the laterality of RESTLESS LEG SYNDROME. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 06:52:00
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\23.0.	Coder Import (b) (4)	28 Jul 2020 14:17:23

US3162006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:24:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	28 Jul 2020 14:17:23
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	28 Jul 2020 14:15:53
User entered 'Restless leg syndrome'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:19
	(b) (4)	

US3162006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'un UNK 1990'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:19

US3162006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:19

US3162006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:24:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:19

US3162006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:24:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:19

US3162006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:24:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:19

US3162006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:24:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered 'Jan 1990'	System	28 Jul 2020 14:15:19

US3162006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:24:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered '1990'	System	28 Jul 2020 14:15:19

US3162006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:24:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered empty.	System	28 Jul 2020 14:15:19

US3162006

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:24:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered empty.	System	28 Jul 2020 14:15:19

US3162006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:24:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 14:17:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 14:17:23
Data point term sent to Coder	System	28 Jul 2020 14:15:53
User entered 'osteoporosis'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:34

US3162006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'un UNK 2014'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:34

US3162006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:34

US3162006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:24:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:34

US3162006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:24:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:34

US3162006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:24:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:34

US3162006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:24:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered 'Jan 2014'	System	28 Jul 2020 14:15:34

US3162006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:24:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered '2014'	System	28 Jul 2020 14:15:34

US3162006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:24:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered empty.	System	28 Jul 2020 14:15:34

US3162006

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:24:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered empty.	System	28 Jul 2020 14:15:34

US3162006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:24:55

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 17:48:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Jul 2020 17:48:11
Data point term sent to Coder	System	28 Jul 2020 14:16:56
User entered 'Sciatica (bilateral legs)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:59

US3162006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'un UNK 2015'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:59

US3162006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:59

US3162006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:24:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:59

US3162006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:24:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:59

US3162006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:24:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:15:59

US3162006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:24:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered 'Jan 2015'	System	28 Jul 2020 14:15:59

US3162006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:24:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered '2015'	System	28 Jul 2020 14:15:59

US3162006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:24:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered empty.	System	28 Jul 2020 14:15:59

US3162006

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:24:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered empty.	System	28 Jul 2020 14:15:59

US3162006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:24:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Gastritis (excl infective), PT: Gastritis, LLT: Gastritis - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:20:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 20:20:46
Data point term sent to Coder	System	16 Nov 2020 20:20:01
User entered 'GASTRITIS'	Judith Kirstein (b) (4)	16 Nov 2020 20:19:03

US3162006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'UN UNK 2019'	Judith Kirstein (b) (4)	16 Nov 2020 20:19:03

US3162006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Judith Kirstein (b) (4)	16 Nov 2020 20:19:03

US3162006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:24:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	16 Nov 2020 20:19:03

US3162006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:24:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Judith Kirstein (b) (4)	16 Nov 2020 20:19:03

US3162006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:24:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Judith Kirstein (b) (4)	16 Nov 2020 20:19:03

US3162006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:24:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered 'Jan 2019'	System	16 Nov 2020 20:19:03

US3162006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:24:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered '2019'	System	16 Nov 2020 20:19:03

US3162006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:24:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered empty.	System	16 Nov 2020 20:19:03

US3162006

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:24:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered empty.	System	16 Nov 2020 20:19:03

US3162006

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:24:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 17:04:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 17:04:03
Data point term sent to Coder	System	22 Apr 2021 17:03:06
User entered 'Natural Menopausal'	(b) (4), (b) (6)	22 Apr 2021 17:02:56

US3162006

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'UN UNK 2004'	(b) (4), (b) (6)	22 Apr 2021 17:02:56

US3162006

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:02:56

US3162006

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:24:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Apr 2021 17:02:56

US3162006

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:24:55

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:02:56

US3162006

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:24:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:02:56

US3162006

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:24:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered 'Jan 2004'	System	22 Apr 2021 17:02:56

US3162006

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:24:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered '2004'	System	22 Apr 2021 17:02:56

US3162006

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:24:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered empty.	System	22 Apr 2021 17:02:56

US3162006

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:24:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered empty.	System	22 Apr 2021 17:02:56

US3162006

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:24:55

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Oesophageal spasm, LLT: Esophageal spasm - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 05:28:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 05:28:50
Data point term sent to Coder	System	22 Apr 2021 17:04:07
User entered 'Intermittent esophageal spasm'	(b) (4), (b) (6)	22 Apr 2021 17:03:31

US3162006

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'UN Oct 2019'	(b) (4), (b) (6)	22 Apr 2021 17:03:31

US3162006

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:03:31

US3162006

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:24:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Apr 2021 17:03:31

US3162006

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:24:55

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:03:31

US3162006

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:24:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:03:31

US3162006

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:24:55

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered 'Oct 2019'	System	22 Apr 2021 17:03:31

US3162006

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:24:55

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered '2019'	System	22 Apr 2021 17:03:31

US3162006

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:24:55

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered empty.	System	22 Apr 2021 17:03:31

US3162006

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:24:55

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered empty.	System	22 Apr 2021 17:03:31

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 14:17:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jul 2020 14:17:22
User entered 'Yes (Y)' reason for change: New Information	Jared Bradshaw (b) (4)	28 Jul 2020 14:17:22
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 14:17:14
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:17:14

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 14:17:14

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '16:56'	Jared Bradshaw (b) (4)	28 Jul 2020 14:17:14

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered '27 Jul 2020 16:56'	System	28 Jul 2020 14:17:14

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '61' in	Jared Bradshaw (b) (4)	28 Jul 2020 14:17:14
DataPoint set to visible.	(b) (4) System	28 Jul 2020 01:15:37

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '138.2' lb	Jared Bradshaw (b) (4)	28 Jul 2020 14:17:14
DataPoint set to visible.	(b) (4) System	28 Jul 2020 01:15:37

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
Amendment Manager: User entered '26.16726'	System	16 Sep 2020 23:37:09
User entered '26.2'	System	28 Jul 2020 14:17:14
DataPoint set to visible.	System	28 Jul 2020 01:15:37

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered 'kg/m2'	System	28 Jul 2020 14:17:14
DataPoint set to visible.	System	28 Jul 2020 01:15:37

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 02:46:31
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' answered with 'updated' (Site from DM).	Jourdan Manfred (b) (4)	03 Sep 2020 00:27:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	03 Sep 2020 00:27:17
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 16:51:03
User entered '97.6' F	Jared Bradshaw (b) (4)	28 Jul 2020 14:17:14

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" field accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 17:26:09
Query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" field accordingly.' answered with 'Updated.' (Site from DM).	Cynthia Kunakom (b) (4)	24 Sep 2020 17:02:26
User entered empty; reason for change Data Entry Error	Cynthia Kunakom (b) (4)	24 Sep 2020 17:02:21
User opened query 'Per CDM: Since Temperature is ND, route of measurement is not required. Please update "Route of measurement" field accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 11:56:26
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:17:14

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:17:14

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4)	03 Sep 2020 00:27:17
User entered '66'	Jared Bradshaw (b) (4)	28 Jul 2020 14:17:14

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered 'bpm'	System	28 Jul 2020 14:17:14

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4)	03 Sep 2020 00:27:17
User entered '19'	Jared Bradshaw (b) (4)	28 Jul 2020 14:17:14

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered 'breaths/min'	System	28 Jul 2020 14:17:14

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4)	03 Sep 2020 00:27:17
User entered '101'	Jared Bradshaw (b) (4)	28 Jul 2020 14:17:14

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered 'mmHg'	System	28 Jul 2020 14:17:14

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Jourdan Manfred (b) (4)	03 Sep 2020 00:27:17
User entered '59'	Jared Bradshaw (b) (4)	28 Jul 2020 14:17:14

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User entered 'mmHg'	System	28 Jul 2020 14:17:14

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41

US3162006

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41

US3162006

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:17:43

US3162006

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	27 Aug 2020 12:28:55
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		24 Aug 2020 23:37:16
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 14:17:43
	(b) (4)	

US3162006

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:24:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 14:20:51

US3162006

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:24:55

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:20:51

US3162006

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:24:55

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:20:51

US3162006

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:24:55

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:20:51

US3162006

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:24:55

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:20:51

US3162006

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:24:55

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:20:51

US3162006

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:24:55

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	System	12 Aug 2020 20:14:52
User entered 'UN UNK 2004' reason for change: New Information	Jourdan Manfred (b) (4)	12 Aug 2020 20:14:52
User opened query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	System	28 Jul 2020 14:20:51
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:20:51

US3162006

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:24:55

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:20:51

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

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 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

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 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

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 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

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 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

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 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

[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 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

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 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

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 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

[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 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

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 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

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 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 14:21:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Jul 2020 14:21:51
User entered 'No (N)' reason for change: New Information	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:51
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Jul 2020 14:21:43
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'none'	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

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 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

[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 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

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 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'I'	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:24:55

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:19:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:21:43

US3162006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:22:04

US3162006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 14:22:04

US3162006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Clinic (Clinic)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:22:04

US3162006

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'VISIT1'	System	28 Jul 2020 14:22:04

US3162006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:24:55

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '27 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 00:34:35

US3162006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:24:55

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:05:38
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:05:38
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	28 Jul 2020 00:34:35
User entered '184042' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 00:34:35

US3162006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:24:55

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Jul 2020 00:34:35

US3162006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:24:55

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)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:22:16

US3162006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:24:55

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)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:22:16

US3162006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:24:55

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:22:16

US3162006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:24:55

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:22:16

US3162006

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:24:55

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:22:16

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:24:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:47:29
User entered '61' in	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:24:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:47:29
User entered '62.7' kg	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:24:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:47:29
User entered '61' in	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:24:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:47:29
User entered '62.7' kg	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User accepted default value 'Pre-Dose (PREDOSE)'	Jared Bradshaw (b) (4) (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	28 Jul 2020 14:30:22
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	28 Jul 2020 14:24:36
User entered '16:56'	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered '27 Jul 2020 16:56'	System	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '97.6' F	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '66'	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'bpm'	System	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '19'	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'breaths/min'	System	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '101'	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'mmHg'	System	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 10:43:34
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS and not AE. Subject asymptomatic' (Site from System).	Judith Kirstein (b) (4)	17 Sep 2020 19:52:30
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:37:09
User entered '59'	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'mmHg'	System	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:24:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:47:29
User entered '61' in	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:24:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered missing code ND - Not Done; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:47:29
User entered '62.7' kg	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User accepted default value 'Post-Dose (POSTDOSE)'	Jared Bradshaw (b) (4) (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	05 Aug 2020 18:18:18
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'This data is correct ' (Site from System).	Jared Bradshaw (b) (4)	28 Jul 2020 14:31:10
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		28 Jul 2020 14:30:22
User entered '18:38'	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered '27 Jul 2020 18:38'	System	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Temperature is not less than 38.0 C/100.4 F as required by protocol on day of first vaccination. Please confirm temperature is correct. (Exclusion criterion 4)' (Site from System).	System	28 Jul 2020 14:31:43
Query 'Temperature is not less than 38.0 C/100.4 F as required by protocol on day of first vaccination. Please confirm temperature is correct. (Exclusion criterion 4)' answered by data change (Site from System).	System	28 Jul 2020 14:31:43
User entered '97.4' F reason for change: New Information	Jared Bradshaw (b) (4)	28 Jul 2020 14:31:43
User opened query 'Temperature is not less than 38.0 C/100.4 F as required by protocol on day of first vaccination. Please confirm temperature is correct. (Exclusion criterion 4)' (Site from System).	System	28 Jul 2020 14:24:36
User entered '97.4' C	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '60'	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'bpm'	System	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '18'	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'breaths/min'	System	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '129'	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'mmHg'	System	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '78'	Jared Bradshaw (b) (4)	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'mmHg'	System	28 Jul 2020 14:24:36

US3162006

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:47:16
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:26:06

US3162006

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty; reason for change Data Entry Error	Jared Bradshaw (b) (4)	08 Aug 2020 19:47:16
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 14:26:06

US3162006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	28 Jul 2020 01:17:33
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	28 Jul 2020 01:17:33
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	28 Jul 2020 01:16:10
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 01:16:10

US3162006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 01:16:10

US3162006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

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)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 01:16:10

US3162006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'MRNA-1273 OR PLACEBO'	System	28 Jul 2020 01:16:10

US3162006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 01:16:10

US3162006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '18:00' reason for change: New Information	Jared Bradshaw (b) (4)	28 Jul 2020 14:30:22
User entered '06:00'	Jared Bradshaw (b) (4)	28 Jul 2020 01:16:10

US3162006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered '27 Jul 2020 18:00'	System	28 Jul 2020 14:30:22
User entered '27 Jul 2020 06:00'	System	28 Jul 2020 01:16:10

US3162006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	28 Jul 2020 01:17:33
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 01:16:10

US3162006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'ONCE'	System	28 Jul 2020 01:16:10

US3162006

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'INTRAMUSCULAR'	System	28 Jul 2020 01:16:10

US3162006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:32:23

US3162006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 14:32:23

US3162006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '17:50'	Jared Bradshaw (b) (4)	28 Jul 2020 14:32:23

US3162006

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered '27 Jul 2020 17:50'	System	28 Jul 2020 14:32:23

US3162006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:24:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '27 Jul 2020'	Jared Bradshaw (b) (4)	28 Jul 2020 14:32:42

US3162006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:24:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:32:42

US3162006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:24:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:32:42

US3162006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:24:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '17:56'	Jared Bradshaw (b) (4)	28 Jul 2020 14:32:42

US3162006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:24:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered '27 Jul 2020 17:56'	System	28 Jul 2020 14:32:42

US3162006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:24:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:32:42

US3162006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:24:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:32:42

US3162006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:24:55

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	28 Jul 2020 14:32:42

US3162006

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:24:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered empty.	System	28 Jul 2020 14:32:42

US3162006

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	28 Jul 2020 14:32:47

US3162006

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'I'	System	28 Jul 2020 14:32:47

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '27 Jul 2020 18:20'	System	28 Jul 2020 14:30:22
User entered '27 Jul 2020 06:20'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '27 Jul 2020 20:50'	System	28 Jul 2020 14:30:22
User entered '27 Jul 2020 08:50'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-27T18:44:11', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '2e7d6b9a-1c73-4af9-b507-44a7ef0b6dec' User entered 'Yes (Y)'	System	28 Jul 2020 01:44:50
	System	28 Jul 2020 01:44:50

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-27T18:44:23', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '2e7d6b9a-1c73-4af9-b507-44a7ef0b6dec' User entered '97.4'	System	28 Jul 2020 01:44:50
	System	28 Jul 2020 01:44:50

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-27T18:44:32', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '2e7d6b9a-1c73-4af9-b507-44a7ef0b6dec'	System	28 Jul 2020 01:44:50
User entered 'No (N)'	System	28 Jul 2020 01:44:50

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-27T18:44:47', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '2e7d6b9a-1c73-4af9-b507-44a7ef0b6dec' User entered '27 Jul 2020 18:44'	System	28 Jul 2020 01:44:50
	System	28 Jul 2020 01:44:50

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '27 Jul 2020 09:45'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '28 Jul 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 2'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:24:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:24:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:24:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:24:55

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:24:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '28 Jul 2020 12:00'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 3'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:24:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-29T18:07:03', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c7a1bb5a-d50a-4ab8-a189-f9126142500b' User entered 'Yes (Y)'	System	30 Jul 2020 01:12:19
	System	30 Jul 2020 01:12:19

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:24:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-29T18:10:03', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c7a1bb5a-d50a-4ab8-a189-f9126142500b' User entered '98.0'	System	30 Jul 2020 01:12:19
	System	30 Jul 2020 01:12:19

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:24:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-29T18:10:20', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c7a1bb5a-d50a-4ab8-a189-f9126142500b' User entered 'No (N)'	System	30 Jul 2020 01:12:19
	System	30 Jul 2020 01:12:19

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-29T18:12:17', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c7a1bb5a-d50a-4ab8-a189-f9126142500b' User entered '29 Jul 2020 18:12'	System	30 Jul 2020 01:12:19
	System	30 Jul 2020 01:12:19

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 4'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:24:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:24:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:24:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:24:55

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:24:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 5'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:24:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-08-01T10:06:44', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'f96f5975-4d8a-40cc-9122-87fe638f0bca' User entered 'Yes (Y)'	System	01 Aug 2020 17:07:25
	System	01 Aug 2020 17:07:25

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:24:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-08-01T10:06:58', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'f96f5975-4d8a-40cc-9122-87fe638f0bca' User entered '97.2'	System	01 Aug 2020 17:07:25
	System	01 Aug 2020 17:07:25

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:24:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-08-01T10:07:05', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'f96f5975-4d8a-40cc-9122-87fe638f0bca'	System	01 Aug 2020 17:07:25
User entered 'No (N)'	System	01 Aug 2020 17:07:25

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-08-01T10:07:23', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'f96f5975-4d8a-40cc-9122-87fe638f0bca' User entered '01 Aug 2020 10:07'	System	01 Aug 2020 17:07:25
	System	01 Aug 2020 17:07:25

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 6'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:24:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:24:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:24:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:24:55

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:24:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 7'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:24:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:24:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:24:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:24:55

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:24:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '27 Jul 2020 18:20'	System	28 Jul 2020 14:30:22
User entered '27 Jul 2020 06:20'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '27 Jul 2020 20:50'	System	28 Jul 2020 14:30:22
User entered '27 Jul 2020 08:50'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-27T18:45:05', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'd19d73e6-1837-46c0-be18-1ee41b35730a' User entered 'None (1)'	System	28 Jul 2020 01:45:51
	System	28 Jul 2020 01:45:51

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-27T18:45:10', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'd19d73e6-1837-46c0-be18-1ee41b35730a' User entered 'No (N)'	System	28 Jul 2020 01:45:51
	System	28 Jul 2020 01:45:51

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-27T18:45:17', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'd19d73e6-1837-46c0-be18-1ee41b35730a' User entered 'No (N)'	System	28 Jul 2020 01:45:51
	System	28 Jul 2020 01:45:51

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-27T18:45:36', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'd19d73e6-1837-46c0-be18-1ee41b35730a' User entered 'None (1)'	System	28 Jul 2020 01:45:51
	System	28 Jul 2020 01:45:51

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-27T18:45:49', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'd19d73e6-1837-46c0-be18-1ee41b35730a' User entered '27 Jul 2020 18:45'	System	28 Jul 2020 01:45:51
	System	28 Jul 2020 01:45:51

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '27 Jul 2020 09:45'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '28 Jul 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 2'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '28 Jul 2020 12:00'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 3'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-29T18:13:29', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'a710dc0d-a67f-4ba2-af45-2b0f87d14ed2'	System	30 Jul 2020 01:15:17
User entered 'None (1)'	System	30 Jul 2020 01:15:17

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-29T18:13:46', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'a710dc0d-a67f-4ba2-af45-2b0f87d14ed2'	System	30 Jul 2020 01:15:17
User entered 'No (N)'	System	30 Jul 2020 01:15:17

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-29T18:14:17', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'a710dc0d-a67f-4ba2-af45-2b0f87d14ed2'	System	30 Jul 2020 01:15:17
User entered 'No (N)'	System	30 Jul 2020 01:15:17

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-29T18:14:51', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'a710dc0d-a67f-4ba2-af45-2b0f87d14ed2'	System	30 Jul 2020 01:15:17
User entered 'None (1)'	System	30 Jul 2020 01:15:17

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-29T18:15:16', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'a710dc0d-a67f-4ba2-af45-2b0f87d14ed2'	System	30 Jul 2020 01:15:17
User entered '29 Jul 2020 18:15'	System	30 Jul 2020 01:15:17

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 4'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 5'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 6'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 7'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '27 Jul 2020 18:20'	System	28 Jul 2020 14:30:22
User entered '27 Jul 2020 06:20'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '27 Jul 2020 20:50'	System	28 Jul 2020 14:30:22
User entered '27 Jul 2020 08:50'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 1, after vaccination (at home)'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-27T18:46:04', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '0c04acec-3b02-4f77-a1b2-067af1e95e46' User entered 'None (0)'	System	28 Jul 2020 01:46:54
	System	28 Jul 2020 01:46:54

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-27T18:46:09', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '0c04acec-3b02-4f77-a1b2-067af1e95e46' User entered 'None (0)'	System	28 Jul 2020 01:46:54
	System	28 Jul 2020 01:46:54

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-27T18:46:14', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '0c04acec-3b02-4f77-a1b2-067af1e95e46' User entered 'None (0)'	System	28 Jul 2020 01:46:54
	System	28 Jul 2020 01:46:54

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-27T18:46:18', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '0c04acec-3b02-4f77-a1b2-067af1e95e46' User entered 'None (0)'	System	28 Jul 2020 01:46:54
	System	28 Jul 2020 01:46:54

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-27T18:46:22', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '0c04acec-3b02-4f77-a1b2-067af1e95e46' User entered 'None (0)'	System	28 Jul 2020 01:46:54
	System	28 Jul 2020 01:46:54

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-27T18:46:25', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '0c04acec-3b02-4f77-a1b2-067af1e95e46' User entered 'None (0)'	System	28 Jul 2020 01:46:54
	System	28 Jul 2020 01:46:54

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-27T18:46:41', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '0c04acec-3b02-4f77-a1b2-067af1e95e46' User entered 'No (N)'	System	28 Jul 2020 01:46:54
	System	28 Jul 2020 01:46:54

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-27T18:46:49', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '0c04acec-3b02-4f77-a1b2-067af1e95e46' User entered '27 Jul 2020 18:46'	System	28 Jul 2020 01:46:54
	System	28 Jul 2020 01:46:54

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '27 Jul 2020 09:45'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '28 Jul 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 2'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '28 Jul 2020 12:00'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '29 Jul 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 3'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-29T22:24:22', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c18c26fe-43de-4ff3-9666-4ffd71804b16' User entered 'None (0)'	System	30 Jul 2020 05:28:58
	System	30 Jul 2020 05:28:58

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-29T22:24:44', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c18c26fe-43de-4ff3-9666-4ffd71804b16' User entered 'None (0)'	System	30 Jul 2020 05:28:58
	System	30 Jul 2020 05:28:58

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-29T22:27:43', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c18c26fe-43de-4ff3-9666-4ffd71804b16' User entered 'None (0)'	System	30 Jul 2020 05:28:58
	System	30 Jul 2020 05:28:58

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-29T22:27:47', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c18c26fe-43de-4ff3-9666-4ffd71804b16' User entered 'None (0)'	System	30 Jul 2020 05:28:58
	System	30 Jul 2020 05:28:58

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-29T22:27:52', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c18c26fe-43de-4ff3-9666-4ffd71804b16' User entered 'None (0)'	System	30 Jul 2020 05:28:58
	System	30 Jul 2020 05:28:58

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-29T22:27:55', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c18c26fe-43de-4ff3-9666-4ffd71804b16' User entered 'None (0)'	System	30 Jul 2020 05:28:58
	System	30 Jul 2020 05:28:58

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-29T22:28:03', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c18c26fe-43de-4ff3-9666-4ffd71804b16'	System	30 Jul 2020 05:28:58
User entered 'No (N)'	System	30 Jul 2020 05:28:58

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-07-29T22:28:56', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c18c26fe-43de-4ff3-9666-4ffd71804b16' User entered '29 Jul 2020 22:28'	System	30 Jul 2020 05:28:58
	System	30 Jul 2020 05:28:58

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '29 Jul 2020 12:00'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '30 Jul 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 4'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '30 Jul 2020 12:00'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '31 Jul 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 5'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-08-01T10:08:07', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'fc7b9aaf-6dc4-4232-8c33-a28cfab46cd2'	System	01 Aug 2020 17:08:57
User entered 'None (0)'	System	01 Aug 2020 17:08:57

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-08-01T10:08:10', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'fc7b9aaf-6dc4-4232-8c33-a28cfab46cd2' User entered 'None (0)'	System	01 Aug 2020 17:08:57
	System	01 Aug 2020 17:08:57

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-08-01T10:08:17', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'fc7b9aaf-6dc4-4232-8c33-a28cfab46cd2' User entered 'None (0)'	System	01 Aug 2020 17:08:57
	System	01 Aug 2020 17:08:57

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-08-01T10:08:24', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'fc7b9aaf-6dc4-4232-8c33-a28cfab46cd2' User entered 'None (0)'	System	01 Aug 2020 17:08:57
	System	01 Aug 2020 17:08:57

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-08-01T10:08:28', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'fc7b9aaf-6dc4-4232-8c33-a28cfab46cd2' User entered 'None (0)'	System	01 Aug 2020 17:08:57
	System	01 Aug 2020 17:08:57

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-08-01T10:08:30', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'fc7b9aaf-6dc4-4232-8c33-a28cfab46cd2' User entered 'None (0)'	System	01 Aug 2020 17:08:57
	System	01 Aug 2020 17:08:57

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-08-01T10:08:37', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'fc7b9aaf-6dc4-4232-8c33-a28cfab46cd2'	System	01 Aug 2020 17:08:57
User entered 'No (N)'	System	01 Aug 2020 17:08:57

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C286B007-045D-4E55-BD40-B8FA5E5F3143)', Time: '2020-08-01T10:08:53', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'fc7b9aaf-6dc4-4232-8c33-a28cfab46cd2'	System	01 Aug 2020 17:08:57
User entered '01 Aug 2020 10:08'	System	01 Aug 2020 17:08:57

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '31 Jul 2020 12:00'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '01 Aug 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 6'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '01 Aug 2020 12:00'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '02 Aug 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 7'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '02 Aug 2020 12:00'	System	28 Jul 2020 01:16:10

US3162006

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '03 Aug 2020 11:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:46:07

US3162006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '3 Aug 2020'	Jared Bradshaw (b) (4)	05 Aug 2020 04:46:07

US3162006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:46:07

US3162006

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	05 Aug 2020 04:46:07

US3162006

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	05 Aug 2020 04:46:11

US3162006

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'I'	System	05 Aug 2020 04:46:11

US3162006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	12 Aug 2020 05:16:40

US3162006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '10 Aug 2020'	Jared Bradshaw (b) (4)	12 Aug 2020 05:16:40

US3162006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4)	12 Aug 2020 05:16:40

US3162006

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	12 Aug 2020 05:16:40

US3162006

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	12 Aug 2020 05:16:28

US3162006

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'I'	System	12 Aug 2020 05:16:28

US3162006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	18 Aug 2020 05:12:46

US3162006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '17 Aug 2020'	Jared Bradshaw (b) (4)	18 Aug 2020 05:12:46

US3162006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4)	18 Aug 2020 05:12:46

US3162006

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	18 Aug 2020 05:12:46

US3162006

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	18 Aug 2020 05:12:53

US3162006

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'I'	System	18 Aug 2020 05:12:53

US3162006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 23:37:16

US3162006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '24 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 23:37:16

US3162006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Aug 2020 23:37:16

US3162006

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'VISIT2'	System	24 Aug 2020 23:37:16

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User accepted default value 'Pre-Dose (PREDOSE)'	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24
	(b) (4)	

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 22:49:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 22:49:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:49:51
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 15:27:24
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '24 Aug 2020' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:49:51
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '16:13' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:49:51
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered '24 Aug 2020 16:13'	System	02 Sep 2020 22:49:51
User entered empty.	System	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '97.4' F reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:49:51
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Oral (Oral)' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:49:51
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '68' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:49:51
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'bpm'	System	02 Sep 2020 22:49:51
User entered empty.	System	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '15' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:49:51
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'breaths/min'	System	02 Sep 2020 22:49:51
User entered empty.	System	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '130' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:49:51
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'mmHg'	System	02 Sep 2020 22:49:51
User entered empty.	System	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '87' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:49:51
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'mmHg'	System	02 Sep 2020 22:49:51
User entered empty.	System	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User accepted default value 'Post-Dose (POSTDOSE)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 22:49:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Sep 2020 22:49:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:49:51
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 15:27:24
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '24 Aug 2020' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:49:51
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '17:39' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:49:51
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered '24 Aug 2020 17:39'	System	02 Sep 2020 22:49:51
User entered empty.	System	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 22:50:02
User entered '97.5' F reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:50:02
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Sep 2020 22:49:51
User entered '97.5' (non-conformant).	Jourdan Manfred (b) (4)	02 Sep 2020 22:49:51
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Oral (Oral)' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:49:51
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '57' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:49:51
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'bpm'	System	02 Sep 2020 22:49:51
User entered empty.	System	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '15' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:49:51
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'breaths/min'	System	02 Sep 2020 22:49:51
User entered empty.	System	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '135' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:49:51
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'mmHg'	System	02 Sep 2020 22:49:51
User entered empty.	System	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '75' reason for change: Data Entry Error	Jourdan Manfred (b) (4)	02 Sep 2020 22:49:51
User entered empty.	Cynthia Kunakom (b) (4)	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'mmHg'	System	02 Sep 2020 22:49:51
User entered empty.	System	28 Aug 2020 15:27:24

US3162006

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	31 Aug 2020 14:39:26

US3162006

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '24 Aug 2020'	Cynthia Kunakom (b) (4)	31 Aug 2020 14:39:26

US3162006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 00:11:29

US3162006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 00:11:29

US3162006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

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)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 00:11:29

US3162006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 00:11:29

US3162006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 00:11:29

US3162006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '17:02'	(b) (4), (b) (6)	25 Aug 2020 00:11:29

US3162006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered '24 Aug 2020 17:02'	System	25 Aug 2020 00:11:29

US3162006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	25 Aug 2020 00:11:29

US3162006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'ONCE'	System	25 Aug 2020 00:11:29

US3162006

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 00:11:29

US3162006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	31 Aug 2020 14:39:41

US3162006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '24 Aug 2020'	Cynthia Kunakom (b) (4)	31 Aug 2020 14:39:41

US3162006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '16:50'	Cynthia Kunakom (b) (4)	31 Aug 2020 14:39:41

US3162006

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered '24 Aug 2020 16:50'	System	31 Aug 2020 14:39:41

US3162006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:24:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '24 Aug 2020'	Cynthia Kunakom (b) (4)	31 Aug 2020 14:40:36

US3162006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:24:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cynthia Kunakom (b) (4)	31 Aug 2020 14:40:36

US3162006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:24:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	31 Aug 2020 14:40:36

US3162006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:24:55

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '16:56'	Cynthia Kunakom (b) (4)	31 Aug 2020 14:40:36

US3162006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:24:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered '24 Aug 2020 16:56'	System	31 Aug 2020 14:40:36

US3162006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:24:55

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cynthia Kunakom (b) (4)	31 Aug 2020 14:40:36

US3162006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:24:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Cynthia Kunakom (b) (4)	31 Aug 2020 14:40:36

US3162006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:24:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Cynthia Kunakom (b) (4)	31 Aug 2020 14:40:36

US3162006

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:24:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered empty.	System	31 Aug 2020 14:40:36

US3162006

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	31 Aug 2020 14:40:48

US3162006

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'I'	System	31 Aug 2020 14:40:48

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T17:24:31', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '99c9db95-f25a-4877-90f5-fdf0ad3f550e' User entered 'Yes (Y)'	System	25 Aug 2020 00:25:40
	System	25 Aug 2020 00:25:40

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T17:24:53', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '99c9db95-f25a-4877-90f5-fdf0ad3f550e' User entered '97.4'	System	25 Aug 2020 00:25:40
	System	25 Aug 2020 00:25:40

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T17:25:09', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '99c9db95-f25a-4877-90f5-fdf0ad3f550e'	System	25 Aug 2020 00:25:40
User entered 'No (N)'	System	25 Aug 2020 00:25:40

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T17:25:37', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '99c9db95-f25a-4877-90f5-fdf0ad3f550e'	System	25 Aug 2020 00:25:40
User entered '24 Aug 2020 17:25'	System	25 Aug 2020 00:25:40

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '24 Aug 2020 17:22'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '24 Aug 2020 19:52'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T22:02:18', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'b83c09e9-8c4c-4f64-9522-1aa93b043f91' User entered 'Yes (Y)'	System	25 Aug 2020 05:03:10
	System	25 Aug 2020 05:03:10

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T22:02:31', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'b83c09e9-8c4c-4f64-9522-1aa93b043f91' User entered '98.0'	System	25 Aug 2020 05:03:10
	System	25 Aug 2020 05:03:10

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T22:02:39', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'b83c09e9-8c4c-4f64-9522-1aa93b043f91'	System	25 Aug 2020 05:03:10
User entered 'No (N)'	System	25 Aug 2020 05:03:10

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T22:03:08', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'b83c09e9-8c4c-4f64-9522-1aa93b043f91'	System	25 Aug 2020 05:03:10
User entered '24 Aug 2020 22:03'	System	25 Aug 2020 05:03:10

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '24 Aug 2020 20:47'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '25 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 2'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:24:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-25T20:13:05', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c9bbb925-db9f-4272-9d56-74192bef9aa1' User entered 'Yes (Y)'	System	26 Aug 2020 03:13:42
	System	26 Aug 2020 03:13:42

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:24:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-25T20:13:18', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c9bbb925-db9f-4272-9d56-74192bef9aa1'	System	26 Aug 2020 03:13:42
User entered '98.6'	System	26 Aug 2020 03:13:42

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:24:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-25T20:13:24', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c9bbb925-db9f-4272-9d56-74192bef9aa1'	System	26 Aug 2020 03:13:42
User entered 'No (N)'	System	26 Aug 2020 03:13:42

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-25T20:13:40', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c9bbb925-db9f-4272-9d56-74192bef9aa1' User entered '25 Aug 2020 20:13'	System	26 Aug 2020 03:13:42
	System	26 Aug 2020 03:13:42

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '25 Aug 2020 12:00'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 3'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:24:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:24:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:24:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:24:55

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:24:55

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 4'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:24:55

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-27T18:08:58', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '29bb637a-0d43-4364-8af0-cab4451e395d' User entered 'Yes (Y)'	System	28 Aug 2020 01:09:33
	System	28 Aug 2020 01:09:33

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:24:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-27T18:09:09', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '29bb637a-0d43-4364-8af0-cab4451e395d' User entered '98.7'	System	28 Aug 2020 01:09:33
	System	28 Aug 2020 01:09:33

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:24:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-27T18:09:14', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '29bb637a-0d43-4364-8af0-cab4451e395d' User entered 'No (N)'	System	28 Aug 2020 01:09:33
	System	28 Aug 2020 01:09:33

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-27T18:09:29', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '29bb637a-0d43-4364-8af0-cab4451e395d' User entered '27 Aug 2020 18:09'	System	28 Aug 2020 01:09:33
	System	28 Aug 2020 01:09:33

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 5'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:24:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-28T21:43:56', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'b874550e-998e-4e74-ad4e-2577d99c3ef4' User entered 'Yes (Y)'	System	29 Aug 2020 04:44:29
	System	29 Aug 2020 04:44:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:24:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-28T21:44:06', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'b874550e-998e-4e74-ad4e-2577d99c3ef4' User entered '98.3'	System	29 Aug 2020 04:44:29
	System	29 Aug 2020 04:44:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:24:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-28T21:44:17', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'b874550e-998e-4e74-ad4e-2577d99c3ef4' User entered 'No (N)'	System	29 Aug 2020 04:44:29
	System	29 Aug 2020 04:44:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-28T21:44:28', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'b874550e-998e-4e74-ad4e-2577d99c3ef4' User entered '28 Aug 2020 21:44'	System	29 Aug 2020 04:44:29
	System	29 Aug 2020 04:44:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 6'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:24:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-29T19:50:43', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'aa40a902-8fcc-4587-afdd-af7a88a41e39'	System	30 Aug 2020 02:52:38
User entered 'Yes (Y)'	System	30 Aug 2020 02:52:38

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:24:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-29T19:52:14', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'aa40a902-8fcc-4587-afdd-af7a88a41e39' User entered '98.1'	System	30 Aug 2020 02:52:38
	System	30 Aug 2020 02:52:38

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:24:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-29T19:52:22', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'aa40a902-8fcc-4587-afdd-af7a88a41e39'	System	30 Aug 2020 02:52:38
User entered 'No (N)'	System	30 Aug 2020 02:52:38

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-29T19:52:33', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'aa40a902-8fcc-4587-afdd-af7a88a41e39'	System	30 Aug 2020 02:52:38
User entered '29 Aug 2020 19:52'	System	30 Aug 2020 02:52:38

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 7'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:24:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-30T21:01:21', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'eace9eed-84f7-4e97-a998-12defcba7a14' User entered 'Yes (Y)'	System	31 Aug 2020 04:02:00
	System	31 Aug 2020 04:02:00

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:24:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-30T21:01:36', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'eace9eed-84f7-4e97-a998-12defcba7a14' User entered '98.1'	System	31 Aug 2020 04:02:00
	System	31 Aug 2020 04:02:00

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:24:55

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-30T21:01:44', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'eace9eed-84f7-4e97-a998-12defcba7a14' User entered 'No (N)'	System	31 Aug 2020 04:02:00
	System	31 Aug 2020 04:02:00

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-30T21:01:57', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'eace9eed-84f7-4e97-a998-12defcba7a14' User entered '30 Aug 2020 21:01'	System	31 Aug 2020 04:02:00
	System	31 Aug 2020 04:02:00

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T17:26:25', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '47d47f46-fc08-408c-843e-287f0c494305'	System	25 Aug 2020 00:28:36
User entered 'None (1)'	System	25 Aug 2020 00:28:36

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T17:27:27', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '47d47f46-fc08-408c-843e-287f0c494305'	System	25 Aug 2020 00:28:36
User entered 'No (N)'	System	25 Aug 2020 00:28:36

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T17:27:32', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '47d47f46-fc08-408c-843e-287f0c494305' User entered 'No (N)'	System	25 Aug 2020 00:28:36
	System	25 Aug 2020 00:28:36

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T17:28:18', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '47d47f46-fc08-408c-843e-287f0c494305'	System	25 Aug 2020 00:28:36
User entered 'None (1)'	System	25 Aug 2020 00:28:36

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T17:28:33', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '47d47f46-fc08-408c-843e-287f0c494305'	System	25 Aug 2020 00:28:36
User entered '24 Aug 2020 17:28'	System	25 Aug 2020 00:28:36

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '24 Aug 2020 17:22'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '24 Aug 2020 19:52'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T22:05:44', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '05f1e3ab-d041-4232-8671-dedf77179694' User entered 'None (1)'	System	25 Aug 2020 05:07:32
	System	25 Aug 2020 05:07:32

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T22:07:01', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '05f1e3ab-d041-4232-8671-dedf77179694' User entered 'No (N)'	System	25 Aug 2020 05:07:32
	System	25 Aug 2020 05:07:32

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T22:07:08', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '05f1e3ab-d041-4232-8671-dedf77179694' User entered 'No (N)'	System	25 Aug 2020 05:07:32
	System	25 Aug 2020 05:07:32

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T22:07:13', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '05f1e3ab-d041-4232-8671-dedf77179694' User entered 'None (1)'	System	25 Aug 2020 05:07:32
	System	25 Aug 2020 05:07:32

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T22:07:30', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '05f1e3ab-d041-4232-8671-dedf77179694' User entered '24 Aug 2020 22:07'	System	25 Aug 2020 05:07:32
	System	25 Aug 2020 05:07:32

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '24 Aug 2020 20:47'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '25 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 2'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-25T20:13:51', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '3720a134-25a0-468f-b619-2940885334b6'	System	26 Aug 2020 03:14:17
User entered 'None (1)'	System	26 Aug 2020 03:14:17

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-25T20:13:58', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '3720a134-25a0-468f-b619-2940885334b6'	System	26 Aug 2020 03:14:17
User entered 'No (N)'	System	26 Aug 2020 03:14:17

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-25T20:14:02', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '3720a134-25a0-468f-b619-2940885334b6'	System	26 Aug 2020 03:14:17
User entered 'No (N)'	System	26 Aug 2020 03:14:17

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-25T20:14:08', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '3720a134-25a0-468f-b619-2940885334b6'	System	26 Aug 2020 03:14:17
User entered 'None (1)'	System	26 Aug 2020 03:14:17

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-25T20:14:15', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '3720a134-25a0-468f-b619-2940885334b6' User entered '25 Aug 2020 20:14'	System	26 Aug 2020 03:14:17
	System	26 Aug 2020 03:14:17

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '25 Aug 2020 12:00'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 3'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 4'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-27T18:09:43', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'e9afdda2-cb4d-408a-bcaa-5a4cdb84202e' User entered 'None (1)'	System	28 Aug 2020 01:10:11
	System	28 Aug 2020 01:10:11

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-27T18:09:48', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'e9afdda2-cb4d-408a-bcaa-5a4cdb84202e' User entered 'No (N)'	System	28 Aug 2020 01:10:11
	System	28 Aug 2020 01:10:11

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-27T18:09:52', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'e9afdda2-cb4d-408a-bcaa-5a4cdb84202e' User entered 'No (N)'	System	28 Aug 2020 01:10:11
	System	28 Aug 2020 01:10:11

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-27T18:09:57', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'e9afdda2-cb4d-408a-bcaa-5a4cdb84202e' User entered 'None (1)'	System	28 Aug 2020 01:10:11
	System	28 Aug 2020 01:10:11

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-27T18:10:06', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'e9afdda2-cb4d-408a-bcaa-5a4cdb84202e'	System	28 Aug 2020 01:10:11
User entered '27 Aug 2020 18:10'	System	28 Aug 2020 01:10:11

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 5'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-28T21:44:44', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '7271065c-31d7-4ab6-98dc-90baf8e949ce'	System	29 Aug 2020 04:45:04
User entered 'None (1)'	System	29 Aug 2020 04:45:04

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-28T21:44:47', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '7271065c-31d7-4ab6-98dc-90baf8e949ce'	System	29 Aug 2020 04:45:04
User entered 'No (N)'	System	29 Aug 2020 04:45:04

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-28T21:44:51', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '7271065c-31d7-4ab6-98dc-90baf8e949ce' User entered 'No (N)'	System	29 Aug 2020 04:45:04
	System	29 Aug 2020 04:45:04

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-28T21:44:55', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '7271065c-31d7-4ab6-98dc-90baf8e949ce' User entered 'None (1)'	System	29 Aug 2020 04:45:04
	System	29 Aug 2020 04:45:04

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-28T21:45:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '7271065c-31d7-4ab6-98dc-90baf8e949ce' User entered '28 Aug 2020 21:45'	System	29 Aug 2020 04:45:04
	System	29 Aug 2020 04:45:04

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 6'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 7'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T17:28:48', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '55910f7e-df43-42c6-b3e9-c49725c4d181' User entered 'None (0)'	System	25 Aug 2020 00:29:48
	System	25 Aug 2020 00:29:48

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T17:28:55', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '55910f7e-df43-42c6-b3e9-c49725c4d181' User entered 'None (0)'	System	25 Aug 2020 00:29:48
	System	25 Aug 2020 00:29:48

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T17:29:05', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '55910f7e-df43-42c6-b3e9-c49725c4d181' User entered 'None (0)'	System	25 Aug 2020 00:29:48
	System	25 Aug 2020 00:29:48

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T17:29:10', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '55910f7e-df43-42c6-b3e9-c49725c4d181' User entered 'None (0)'	System	25 Aug 2020 00:29:48
	System	25 Aug 2020 00:29:48

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T17:29:14', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '55910f7e-df43-42c6-b3e9-c49725c4d181' User entered 'None (0)'	System	25 Aug 2020 00:29:48
	System	25 Aug 2020 00:29:48

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T17:29:17', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '55910f7e-df43-42c6-b3e9-c49725c4d181' User entered 'None (0)'	System	25 Aug 2020 00:29:48
	System	25 Aug 2020 00:29:48

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T17:29:26', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '55910f7e-df43-42c6-b3e9-c49725c4d181' User entered 'No (N)'	System	25 Aug 2020 00:29:48
	System	25 Aug 2020 00:29:48

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T17:29:46', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '55910f7e-df43-42c6-b3e9-c49725c4d181' User entered '24 Aug 2020 17:29'	System	25 Aug 2020 00:29:48
	System	25 Aug 2020 00:29:48

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '24 Aug 2020 17:22'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '24 Aug 2020 19:52'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T22:03:48', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '6c4b7506-1a1e-4285-8b06-dc68cb2e1a5b' User entered 'None (0)'	System	25 Aug 2020 05:04:42
	System	25 Aug 2020 05:04:42

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T22:03:52', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '6c4b7506-1a1e-4285-8b06-dc68cb2e1a5b' User entered 'None (0)'	System	25 Aug 2020 05:04:42
	System	25 Aug 2020 05:04:42

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T22:03:55', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '6c4b7506-1a1e-4285-8b06-dc68cb2e1a5b' User entered 'None (0)'	System	25 Aug 2020 05:04:42
	System	25 Aug 2020 05:04:42

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T22:04:03', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '6c4b7506-1a1e-4285-8b06-dc68cb2e1a5b' User entered 'None (0)'	System	25 Aug 2020 05:04:42
	System	25 Aug 2020 05:04:42

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T22:04:06', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '6c4b7506-1a1e-4285-8b06-dc68cb2e1a5b' User entered 'None (0)'	System	25 Aug 2020 05:04:42
	System	25 Aug 2020 05:04:42

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T22:04:09', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '6c4b7506-1a1e-4285-8b06-dc68cb2e1a5b' User entered 'None (0)'	System	25 Aug 2020 05:04:42
	System	25 Aug 2020 05:04:42

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T22:04:25', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '6c4b7506-1a1e-4285-8b06-dc68cb2e1a5b' User entered 'No (N)'	System	25 Aug 2020 05:04:42
	System	25 Aug 2020 05:04:42

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-24T22:04:35', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '6c4b7506-1a1e-4285-8b06-dc68cb2e1a5b' User entered '24 Aug 2020 22:04'	System	25 Aug 2020 05:04:42
	System	25 Aug 2020 05:04:42

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '24 Aug 2020 20:47'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '25 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 2'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-25T20:14:24', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '88a3cb9c-bb2c-4117-b367-0751f44c58af' User entered 'None (0)'	System	26 Aug 2020 03:15:07
	System	26 Aug 2020 03:15:07

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-25T20:14:29', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '88a3cb9c-bb2c-4117-b367-0751f44c58af' User entered 'None (0)'	System	26 Aug 2020 03:15:07
	System	26 Aug 2020 03:15:07

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-25T20:14:34', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '88a3cb9c-bb2c-4117-b367-0751f44c58af' User entered 'None (0)'	System	26 Aug 2020 03:15:07
	System	26 Aug 2020 03:15:07

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-25T20:14:38', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '88a3cb9c-bb2c-4117-b367-0751f44c58af' User entered 'None (0)'	System	26 Aug 2020 03:15:07
	System	26 Aug 2020 03:15:07

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-25T20:14:41', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '88a3cb9c-bb2c-4117-b367-0751f44c58af' User entered 'None (0)'	System	26 Aug 2020 03:15:07
	System	26 Aug 2020 03:15:07

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-25T20:14:44', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '88a3cb9c-bb2c-4117-b367-0751f44c58af' User entered 'None (0)'	System	26 Aug 2020 03:15:07
	System	26 Aug 2020 03:15:07

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-25T20:14:58', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '88a3cb9c-bb2c-4117-b367-0751f44c58af' User entered 'No (N)'	System	26 Aug 2020 03:15:07
	System	26 Aug 2020 03:15:07

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-25T20:15:02', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '88a3cb9c-bb2c-4117-b367-0751f44c58af' User entered '25 Aug 2020 20:15'	System	26 Aug 2020 03:15:07
	System	26 Aug 2020 03:15:07

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '25 Aug 2020 12:00'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 3'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 4'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-27T18:10:13', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '4b908c09-244f-4ce0-93ef-325ec50a0c7a' User entered 'None (0)'	System	28 Aug 2020 01:11:04
	System	28 Aug 2020 01:11:04

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-27T18:10:24', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '4b908c09-244f-4ce0-93ef-325ec50a0c7a' User entered 'None (0)'	System	28 Aug 2020 01:11:04
	System	28 Aug 2020 01:11:04

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-27T18:10:30', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '4b908c09-244f-4ce0-93ef-325ec50a0c7a' User entered 'None (0)'	System	28 Aug 2020 01:11:04
	System	28 Aug 2020 01:11:04

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-27T18:10:33', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '4b908c09-244f-4ce0-93ef-325ec50a0c7a' User entered 'None (0)'	System	28 Aug 2020 01:11:04
	System	28 Aug 2020 01:11:04

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-27T18:10:37', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '4b908c09-244f-4ce0-93ef-325ec50a0c7a' User entered 'None (0)'	System	28 Aug 2020 01:11:04
	System	28 Aug 2020 01:11:04

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-27T18:10:40', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '4b908c09-244f-4ce0-93ef-325ec50a0c7a' User entered 'None (0)'	System	28 Aug 2020 01:11:04
	System	28 Aug 2020 01:11:04

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-27T18:10:46', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '4b908c09-244f-4ce0-93ef-325ec50a0c7a' User entered 'No (N)'	System	28 Aug 2020 01:11:04
	System	28 Aug 2020 01:11:04

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-27T18:11:01', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '4b908c09-244f-4ce0-93ef-325ec50a0c7a' User entered '27 Aug 2020 18:11'	System	28 Aug 2020 01:11:04
	System	28 Aug 2020 01:11:04

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 5'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-28T21:45:05', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'abed20f3-530c-4e30-8ea5-7000c1820e0d' User entered 'None (0)'	System	29 Aug 2020 04:45:31
	System	29 Aug 2020 04:45:31

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-28T21:45:10', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'abed20f3-530c-4e30-8ea5-7000c1820e0d' User entered 'None (0)'	System	29 Aug 2020 04:45:31
	System	29 Aug 2020 04:45:31

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-28T21:45:14', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'abed20f3-530c-4e30-8ea5-7000c1820e0d' User entered 'None (0)'	System	29 Aug 2020 04:45:31
	System	29 Aug 2020 04:45:31

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-28T21:45:16', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'abed20f3-530c-4e30-8ea5-7000c1820e0d' User entered 'None (0)'	System	29 Aug 2020 04:45:31
	System	29 Aug 2020 04:45:31

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-28T21:45:18', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'abed20f3-530c-4e30-8ea5-7000c1820e0d' User entered 'None (0)'	System	29 Aug 2020 04:45:31
	System	29 Aug 2020 04:45:31

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-28T21:45:23', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'abed20f3-530c-4e30-8ea5-7000c1820e0d' User entered 'None (0)'	System	29 Aug 2020 04:45:31
	System	29 Aug 2020 04:45:31

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-28T21:45:25', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'abed20f3-530c-4e30-8ea5-7000c1820e0d' User entered 'No (N)'	System	29 Aug 2020 04:45:31
	System	29 Aug 2020 04:45:31

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-08-28T21:45:29', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'abed20f3-530c-4e30-8ea5-7000c1820e0d' User entered '28 Aug 2020 21:45'	System	29 Aug 2020 04:45:31
	System	29 Aug 2020 04:45:31

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 6'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	25 Aug 2020 00:11:29
User entered 'Day 7'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 00:11:29

US3162006

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:24:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 00:11:29

US3162006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:04:57

US3162006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '31 Aug 2020'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:04:57

US3162006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:04:57

US3162006

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Cynthia Kunakom (b) (4)	03 Sep 2020 19:04:57

US3162006

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	03 Sep 2020 19:05:03

US3162006

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'I'	System	03 Sep 2020 19:05:03

US3162006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	09 Sep 2020 02:51:07

US3162006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '8 Sep 2020'	Jared Bradshaw (b) (4)	09 Sep 2020 02:51:07

US3162006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4)	09 Sep 2020 02:51:07

US3162006

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jared Bradshaw (b) (4)	09 Sep 2020 02:51:07

US3162006

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	09 Sep 2020 02:51:24

US3162006

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'I'	System	09 Sep 2020 02:51:24

US3162006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	15 Sep 2020 17:30:02

US3162006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '14 Sep 2020'	Cynthia Kunakom (b) (4)	15 Sep 2020 17:30:02

US3162006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4)	15 Sep 2020 17:30:02

US3162006

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Cynthia Kunakom (b) (4)	15 Sep 2020 17:30:02

US3162006

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	15 Sep 2020 17:30:08

US3162006

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'I'	System	15 Sep 2020 17:30:08

US3162006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	09 Oct 2020 15:04:44

US3162006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '21 Sep 2020'	Cynthia Kunakom (b) (4)	09 Oct 2020 15:04:44

US3162006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Clinic (Clinic)'	Cynthia Kunakom (b) (4)	09 Oct 2020 15:04:44

US3162006

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'VISIT3'	System	09 Oct 2020 15:04:44

US3162006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	09 Oct 2020 15:05:19

US3162006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '21 Sep 2020'	Cynthia Kunakom (b) (4)	09 Oct 2020 15:05:19

US3162006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '16:33'	Cynthia Kunakom (b) (4)	09 Oct 2020 15:05:19

US3162006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered '21 Sep 2020 16:33'	System	09 Oct 2020 15:05:19

US3162006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '36.6' C	Cynthia Kunakom (b) (4)	09 Oct 2020 15:05:19

US3162006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Oral (Oral)'	Cynthia Kunakom (b) (4)	09 Oct 2020 15:05:19

US3162006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Cynthia Kunakom (b) (4)	09 Oct 2020 15:05:19

US3162006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '64'	Cynthia Kunakom (b) (4)	09 Oct 2020 15:05:19

US3162006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'bpm'	System	09 Oct 2020 15:05:19

US3162006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '14'	Cynthia Kunakom (b) (4)	09 Oct 2020 15:05:19

US3162006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'breaths/min'	System	09 Oct 2020 15:05:19

US3162006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '122'	Cynthia Kunakom (b) (4)	09 Oct 2020 15:05:19

US3162006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'mmHg'	System	09 Oct 2020 15:05:19

US3162006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '62'	Cynthia Kunakom (b) (4)	09 Oct 2020 15:05:19

US3162006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'mmHg'	System	09 Oct 2020 15:05:19

US3162006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43

US3162006

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43

US3162006

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Cynthia Kunakom (b) (4)	09 Oct 2020 15:05:26

US3162006

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Cynthia Kunakom (b) (4)	09 Oct 2020 15:05:26

US3162006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	09 Oct 2020 15:05:35

US3162006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '21 Sep 2020'	Cynthia Kunakom (b) (4)	09 Oct 2020 15:05:35

US3162006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '16:36'	Cynthia Kunakom (b) (4)	09 Oct 2020 15:05:35

US3162006

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered '21 Sep 2020 16:36'	System	09 Oct 2020 15:05:35

US3162006

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	09 Oct 2020 15:05:39

US3162006

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'I'	System	09 Oct 2020 15:05:39

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 64'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-09-29T13:10:48', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'b39acda6-fceb-4325-82e9-c4a855bc4f6a'	System	29 Sep 2020 20:11:34
User entered 'No (N)'	System	29 Sep 2020 20:11:34

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-09-29T13:10:54', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'b39acda6-fceb-4325-82e9-c4a855bc4f6a'	System	29 Sep 2020 20:11:34
User entered 'No (N)'	System	29 Sep 2020 20:11:34

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-09-29T13:11:30', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'b39acda6-fceb-4325-82e9-c4a855bc4f6a' User entered '29 Sep 2020 13:11:30'	System	29 Sep 2020 20:11:34
	System	29 Sep 2020 20:11:34

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered '26 Sep 2020 00:01'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered '30 Sep 2020 23:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 71'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-10-05T14:59:58', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'f2877f81-1b54-4707-b036-83012a8ef7c7'	System	05 Oct 2020 22:00:27
User entered 'No (N)'	System	05 Oct 2020 22:00:27

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-10-05T15:00:02', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'f2877f81-1b54-4707-b036-83012a8ef7c7'	System	05 Oct 2020 22:00:27
User entered 'No (N)'	System	05 Oct 2020 22:00:27

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-10-05T15:00:25', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'f2877f81-1b54-4707-b036-83012a8ef7c7' User entered '05 Oct 2020 15:00:25'	System	05 Oct 2020 22:00:27
	System	05 Oct 2020 22:00:27

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered '03 Oct 2020 00:01'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered '07 Oct 2020 23:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 78'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-10-12T15:17:10', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '73a6f43e-15c1-4927-a9e1-70552c64ea52'	System	12 Oct 2020 22:17:32
User entered 'No (N)'	System	12 Oct 2020 22:17:32

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-10-12T15:17:16', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '73a6f43e-15c1-4927-a9e1-70552c64ea52'	System	12 Oct 2020 22:17:32
User entered 'No (N)'	System	12 Oct 2020 22:17:32

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-10-12T15:17:30', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '73a6f43e-15c1-4927-a9e1-70552c64ea52' User entered '12 Oct 2020 15:17:30'	System	12 Oct 2020 22:17:32
	System	12 Oct 2020 22:17:32

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered '10 Oct 2020 00:01'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered '14 Oct 2020 23:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 92'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E05CD02B-51A9-4318-AFDE-2C5F15BA043A)', Time: '2020-10-28T14:19:48', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'fe5a3c18-8b31-4495-83df-2fd329394816'	System	28 Oct 2020 20:20:17
User entered 'No (N)'	System	28 Oct 2020 20:20:17

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E05CD02B-51A9-4318-AFDE-2C5F15BA043A)', Time: '2020-10-28T14:19:53', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'fe5a3c18-8b31-4495-83df-2fd329394816'	System	28 Oct 2020 20:20:17
User entered 'No (N)'	System	28 Oct 2020 20:20:17

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E05CD02B-51A9-4318-AFDE-2C5F15BA043A)', Time: '2020-10-28T14:20:13', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'fe5a3c18-8b31-4495-83df-2fd329394816' User entered '28 Oct 2020 14:20:13'	System	28 Oct 2020 20:20:17
	System	28 Oct 2020 20:20:17

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered '24 Oct 2020 00:01'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered '28 Oct 2020 23:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 99'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-02T17:03:37', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '6251d9ab-afcd-47c2-a824-2e0c68a4875b' User entered 'No (N)'	System	03 Nov 2020 01:03:59
	System	03 Nov 2020 01:03:59

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-02T17:03:44', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '6251d9ab-afcd-47c2-a824-2e0c68a4875b' User entered 'No (N)'	System	03 Nov 2020 01:03:59
	System	03 Nov 2020 01:03:59

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-02T17:03:57', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '6251d9ab-afcd-47c2-a824-2e0c68a4875b' User entered '02 Nov 2020 17:03:57'	System	03 Nov 2020 01:03:59
	System	03 Nov 2020 01:03:59

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered '31 Oct 2020 00:01'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered '04 Nov 2020 23:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 106'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-09T13:40:46', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'b0b8c7ac-5ff5-4107-a0de-f0482da30981'	System	09 Nov 2020 21:43:20
User entered 'Yes (Y)'	System	09 Nov 2020 21:43:20

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-09T13:40:58', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'b0b8c7ac-5ff5-4107-a0de-f0482da30981'	System	09 Nov 2020 21:43:20
User entered 'No (N)'	System	09 Nov 2020 21:43:20

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-09T13:42:40', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'b0b8c7ac-5ff5-4107-a0de-f0482da30981'	System	09 Nov 2020 21:43:20
User entered 'No (N)'	System	09 Nov 2020 21:43:20

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-09T13:42:57', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'b0b8c7ac-5ff5-4107-a0de-f0482da30981' User entered 'No (N)'	System	09 Nov 2020 21:43:20
	System	09 Nov 2020 21:43:20

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-09T13:43:18', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'b0b8c7ac-5ff5-4107-a0de-f0482da30981' User entered '09 Nov 2020 13:43:18'	System	09 Nov 2020 21:43:20
	System	09 Nov 2020 21:43:20

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered '07 Nov 2020 00:01'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:30:27
Data entry locked.	System	28 Jul 2020 01:16:10
User entered '11 Nov 2020 23:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23
Data entry locked.	System	28 Jul 2020 01:16:10
User entered 'Day 113'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23
Data entry locked.	System	28 Jul 2020 01:16:10
User entered '14 Nov 2020 00:01'	System	28 Jul 2020 01:16:10

US3162006

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:18:23
Data entry locked.	System	28 Jul 2020 01:16:10
User entered '18 Nov 2020 23:59'	System	28 Jul 2020 01:16:10

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:07:06', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered 'Yes (Y)'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:07:27', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered 'Yes (Y)'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:07:46', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b'	System	29 Nov 2020 20:12:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:08:02', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered 'Yes (Y)'	System	29 Nov 2020 20:12:39
	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:10:15', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered '0'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:10:15', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered '0'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:10:15', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered '1'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:10:15', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered '0'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:10:15', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered '0'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:10:15', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered '1'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:10:15', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered '0'	System	29 Nov 2020 20:12:39
	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:10:15', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered '1'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:10:15', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered '1'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:10:15', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered '0'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:10:15', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered '0'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:10:15', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered '0'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:10:15', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered '0'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:10:15', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered '1'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:10:15', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered '1'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:10:15', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered '0'	System	29 Nov 2020 20:12:39
	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:10:15', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered '1'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:12:21', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b'	System	29 Nov 2020 20:12:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:11:07', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered 'No (N)'	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-11-29T12:12:30', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ba583eaf-4525-44a8-a372-3fed2ecca40b' User entered '29 Nov 2020 12:12:30'	System	29 Nov 2020 20:12:39
	System	29 Nov 2020 20:12:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-12-10T14:57:42', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ef3fe3a7-1744-45b0-9d45-14cc1aa44f59'	System	10 Dec 2020 22:58:18
User entered 'No (N)'	System	10 Dec 2020 22:58:18

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-12-10T14:56:53', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ef3fe3a7-1744-45b0-9d45-14cc1aa44f59'	System	10 Dec 2020 22:58:18
User entered 'No (N)'	System	10 Dec 2020 22:58:18

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-12-10T14:58:15', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ef3fe3a7-1744-45b0-9d45-14cc1aa44f59' User entered '10 Dec 2020 14:58:15'	System	10 Dec 2020 22:58:18
	System	10 Dec 2020 22:58:18

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-12-23T07:07:34', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '9a735bec-587d-41ab-b825-10b47311d7a2' User entered 'No (N)'	System	23 Dec 2020 15:07:57
	System	23 Dec 2020 15:07:57

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-12-23T07:07:44', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '9a735bec-587d-41ab-b825-10b47311d7a2'	System	23 Dec 2020 15:07:57
User entered 'No (N)'	System	23 Dec 2020 15:07:57

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-12-23T07:07:54', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '9a735bec-587d-41ab-b825-10b47311d7a2' User entered '23 Dec 2020 07:07:54'	System	23 Dec 2020 15:07:57
	System	23 Dec 2020 15:07:57

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-12-30T07:34:02', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '07b77263-7bbf-40bf-9936-02700175c010'	System	30 Dec 2020 15:34:29
User entered 'No (N)'	System	30 Dec 2020 15:34:29

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-12-30T07:34:07', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '07b77263-7bbf-40bf-9936-02700175c010'	System	30 Dec 2020 15:34:29
User entered 'No (N)'	System	30 Dec 2020 15:34:29

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2020-12-30T07:34:27', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '07b77263-7bbf-40bf-9936-02700175c010' User entered '30 Dec 2020 07:34:27'	System	30 Dec 2020 15:34:29
	System	30 Dec 2020 15:34:29

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-01-10T05:59:57', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'a9ac3eef-8950-497f-8aa9-4e8f23e80eba' User entered 'No (N)'	System	10 Jan 2021 14:00:27
	System	10 Jan 2021 14:00:27

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-01-10T06:00:02', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'a9ac3eef-8950-497f-8aa9-4e8f23e80eba' User entered 'No (N)'	System	10 Jan 2021 14:00:27
	System	10 Jan 2021 14:00:27

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-01-10T06:00:22', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'a9ac3eef-8950-497f-8aa9-4e8f23e80eba' User entered '10 Jan 2021 06:00:22'	System	10 Jan 2021 14:00:27
	System	10 Jan 2021 14:00:27

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-01-14T10:49:22', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c83b0088-1e4f-4cab-9f6b-19eba5035597'	System	14 Jan 2021 18:49:48
User entered 'No (N)'	System	14 Jan 2021 18:49:48

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-01-14T10:49:32', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c83b0088-1e4f-4cab-9f6b-19eba5035597'	System	14 Jan 2021 18:49:48
User entered 'No (N)'	System	14 Jan 2021 18:49:48

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-01-14T10:49:44', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c83b0088-1e4f-4cab-9f6b-19eba5035597' User entered '14 Jan 2021 10:49:44'	System	14 Jan 2021 18:49:48
	System	14 Jan 2021 18:49:48

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-01-21T14:26:51', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'dae7d564-8911-48f2-8959-5ffb44a121be' User entered 'No (N)'	System	21 Jan 2021 22:27:35
	System	21 Jan 2021 22:27:35

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-01-21T14:27:02', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'dae7d564-8911-48f2-8959-5ffb44a121be' User entered 'No (N)'	System	21 Jan 2021 22:27:35

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-01-21T14:27:31', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'dae7d564-8911-48f2-8959-5ffb44a121be' User entered '21 Jan 2021 14:27:31'	System	21 Jan 2021 22:27:35
	System	21 Jan 2021 22:27:35

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-02-03T17:19:46', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'aeb190ed-944a-4437-abed-107b30fe383f' User entered 'No (N)'	System	04 Feb 2021 01:20:12
	System	04 Feb 2021 01:20:12

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-02-03T17:19:52', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'aeb190ed-944a-4437-abed-107b30fe383f' User entered 'No (N)'	System	04 Feb 2021 01:20:12

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-02-03T17:20:05', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'aeb190ed-944a-4437-abed-107b30fe383f' User entered '03 Feb 2021 17:20:05'	System	04 Feb 2021 01:20:12
	System	04 Feb 2021 01:20:12

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-02-11T16:57:24', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'e6b69be9-021f-4e09-97d3-418c05a4ea56'	System	12 Feb 2021 00:57:50
User entered 'No (N)'	System	12 Feb 2021 00:57:50

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-02-11T16:57:29', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'e6b69be9-021f-4e09-97d3-418c05a4ea56'	System	12 Feb 2021 00:57:50
User entered 'No (N)'	System	12 Feb 2021 00:57:50

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-02-11T16:57:46', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'e6b69be9-021f-4e09-97d3-418c05a4ea56' User entered '11 Feb 2021 16:57:46'	System	12 Feb 2021 00:57:50
	System	12 Feb 2021 00:57:50

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-02-28T18:39:49-08:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ef2b0ff3-50fe-45c3-8445-f89e31d6e6f3'	System	01 Mar 2021 02:44:39
User entered 'No (N)'	System	01 Mar 2021 02:44:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-02-28T18:39:55-08:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ef2b0ff3-50fe-45c3-8445-f89e31d6e6f3'	System	01 Mar 2021 02:44:39
User entered 'No (N)'	System	01 Mar 2021 02:44:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-02-28T18:40:09-08:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'ef2b0ff3-50fe-45c3-8445-f89e31d6e6f3'	System	01 Mar 2021 02:44:39
User entered '28 Feb 2021 18:40:09'	System	01 Mar 2021 02:44:39

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-06T02:55:37-08:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '58a839c6-d517-442e-8b6c-a7a42a1bdaa8' User entered 'Yes (Y)'	System	06 Mar 2021 10:57:01
	System	06 Mar 2021 10:57:01

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-06T02:55:43-08:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '58a839c6-d517-442e-8b6c-a7a42a1bdaa8'	System	06 Mar 2021 10:57:01
User entered 'No (N)'	System	06 Mar 2021 10:57:01

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-06T02:55:53-08:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '58a839c6-d517-442e-8b6c-a7a42a1bdaa8'	System	06 Mar 2021 10:57:01
User entered 'No (N)'	System	06 Mar 2021 10:57:01

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-06T02:56:06-08:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '58a839c6-d517-442e-8b6c-a7a42a1bdaa8' User entered 'Yes (Y)'	System	06 Mar 2021 10:57:01
	System	06 Mar 2021 10:57:01

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-06T02:56:26-08:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '58a839c6-d517-442e-8b6c-a7a42a1bdaa8'	System	06 Mar 2021 10:57:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Mar 2021 10:57:01

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-06T02:56:52-08:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '58a839c6-d517-442e-8b6c-a7a42a1bdaa8' User entered '06 Mar 2021 02:56:52'	System	06 Mar 2021 10:57:01
	System	06 Mar 2021 10:57:01

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-12T15:09:43-08:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'f2aed588-b96a-4341-bb2e-3c22f101aa24' User entered 'Yes (Y)'	System	12 Mar 2021 23:11:36
	System	12 Mar 2021 23:11:36

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-12T15:09:49-08:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'f2aed588-b96a-4341-bb2e-3c22f101aa24'	System	12 Mar 2021 23:11:36
User entered 'No (N)'	System	12 Mar 2021 23:11:36

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-12T15:10:04-08:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'f2aed588-b96a-4341-bb2e-3c22f101aa24'	System	12 Mar 2021 23:11:36
User entered 'No (N)'	System	12 Mar 2021 23:11:36

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-12T15:10:36-08:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'f2aed588-b96a-4341-bb2e-3c22f101aa24'	System	12 Mar 2021 23:11:36
User entered 'No (N)'	System	12 Mar 2021 23:11:36

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-12T15:10:59-08:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'f2aed588-b96a-4341-bb2e-3c22f101aa24'	System	12 Mar 2021 23:11:36
User entered '12 Mar 2021 15:10:59'	System	12 Mar 2021 23:11:36

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-17T18:12:15-07:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'a94e82c1-04e9-45ea-ba77-97d729843bc9' User entered 'Yes (Y)'	System	18 Mar 2021 01:14:26
	System	18 Mar 2021 01:14:26

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-17T18:12:22-07:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'a94e82c1-04e9-45ea-ba77-97d729843bc9' User entered 'No (N)'	System	18 Mar 2021 01:14:26
	System	18 Mar 2021 01:14:26

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-17T18:12:29-07:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'a94e82c1-04e9-45ea-ba77-97d729843bc9' User entered 'No (N)'	System	18 Mar 2021 01:14:26
	System	18 Mar 2021 01:14:26

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-17T18:12:43-07:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'a94e82c1-04e9-45ea-ba77-97d729843bc9' User entered 'Yes (Y)'	System	18 Mar 2021 01:14:26
	System	18 Mar 2021 01:14:26

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-17T18:13:18-07:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'a94e82c1-04e9-45ea-ba77-97d729843bc9'	System	18 Mar 2021 01:14:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Mar 2021 01:14:26

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-17T18:13:40-07:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'a94e82c1-04e9-45ea-ba77-97d729843bc9' User entered '17 Mar 2021 18:13:40'	System	18 Mar 2021 01:14:26
	System	18 Mar 2021 01:14:26

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-26T11:28:28-07:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'a3c81064-3ce7-4d70-9676-e43bf2e6a5c7'	System	26 Mar 2021 18:28:46
User entered 'No (N)'	System	26 Mar 2021 18:28:46

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-26T11:28:32-07:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'a3c81064-3ce7-4d70-9676-e43bf2e6a5c7'	System	26 Mar 2021 18:28:46
User entered 'No (N)'	System	26 Mar 2021 18:28:46

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-03-26T11:28:42-07:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'a3c81064-3ce7-4d70-9676-e43bf2e6a5c7' User entered '26 Mar 2021 11:28:42'	System	26 Mar 2021 18:28:46
	System	26 Mar 2021 18:28:46

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-04-09T08:08:42-07:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '21667e40-612d-4640-bc6f-d951b26bb979'	System	09 Apr 2021 15:08:58
User entered 'No (N)'	System	09 Apr 2021 15:08:58

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-04-09T08:08:30-07:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '21667e40-612d-4640-bc6f-d951b26bb979'	System	09 Apr 2021 15:08:58
User entered 'No (N)'	System	09 Apr 2021 15:08:58

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-04-09T08:08:53-07:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '21667e40-612d-4640-bc6f-d951b26bb979'	System	09 Apr 2021 15:08:58
User entered '09 Apr 2021 08:08:53'	System	09 Apr 2021 15:08:58

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-04-14T15:37:14-07:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c51215b4-bfbd-4b78-9af6-4c824712683e' User entered 'No (N)'	System	14 Apr 2021 22:37:36
	System	14 Apr 2021 22:37:36

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-04-14T15:37:20-07:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c51215b4-bfbd-4b78-9af6-4c824712683e' User entered 'No (N)'	System	14 Apr 2021 22:37:36
	System	14 Apr 2021 22:37:36

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-04-14T15:37:32-07:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'c51215b4-bfbd-4b78-9af6-4c824712683e' User entered '14 Apr 2021 15:37:32'	System	14 Apr 2021 22:37:36
	System	14 Apr 2021 22:37:36

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-04-29T10:13:12-07:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'b64a0655-e718-41f6-b46c-87ff3950fcec'	System	29 Apr 2021 17:14:10
User entered 'No (N)'	System	29 Apr 2021 17:14:10

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-04-29T10:12:33-07:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'b64a0655-e718-41f6-b46c-87ff3950fcec'	System	29 Apr 2021 17:14:10
User entered 'No (N)'	System	29 Apr 2021 17:14:10

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-04-29T10:13:22-07:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: 'b64a0655-e718-41f6-b46c-87ff3950fcec' User entered '29 Apr 2021 10:13:22'	System	29 Apr 2021 17:14:10
	System	29 Apr 2021 17:14:10

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 02:18:23

US3162006

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:24:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:18:23
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 02:18:23

US3162006

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:24:55

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-02-28T18:41:12-08:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '485a6c06-4d0c-422e-897e-99b7b6c88fc5'	System	01 Mar 2021 02:45:40
User entered 'No (N)'	System	01 Mar 2021 02:45:40

US3162006

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:24:55

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:08:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3EA74A94-6B15-4B88-863A-FC7FCD60E2DD)', Time: '2021-02-28T18:41:53-08:00', User OID: 'PatientReportedOutcome (US3162006)', ODM File OID: '485a6c06-4d0c-422e-897e-99b7b6c88fc5' User entered '28 Feb 2021 18:41:53'	System	01 Mar 2021 02:45:40
	System	01 Mar 2021 02:45:40

US3162006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:44:28

US3162006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '19 Oct 2020'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:44:28

US3162006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:44:28

US3162006

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Cynthia Kunakom (b) (4)	20 Oct 2020 15:44:28

US3162006

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	20 Oct 2020 15:44:35

US3162006

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 03:59:43
User entered 'I'	System	20 Oct 2020 15:44:35

US3162006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
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	26 Jan 2021 19:05:01
User entered 'No (N)' reason for change: New Information	Judith Kirstein (b) (4)	26 Jan 2021 19:05:01
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	26 Jan 2021 00:46:38
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	26 Jan 2021 00:46:38
User entered 'Yes (Y)' reason for change: New Information	Tiffany Williams (b) (4)	26 Jan 2021 00:46:38
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	25 Jan 2021 17:14:29
User entered 'No (N)'	Tiffany Williams (b) (4)	25 Jan 2021 17:14:29

US3162006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Tiffany Williams (b) (4)	25 Jan 2021 17:14:29

US3162006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty; reason for change Data Entry Error	Judith Kirstein (b) (4)	26 Jan 2021 19:05:01
User entered 'Contact Not Made (CONTACT NOT MADE)'	Tiffany Williams (b) (4)	25 Jan 2021 17:14:29

US3162006

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Subject in convalescent phase' reason for change: Data Entry Error	Judith Kirstein (b) (4)	26 Jan 2021 19:05:01
User entered 'INADVERTENTLY MISSED'	Tiffany Williams (b) (4)	25 Jan 2021 17:14:29

US3162006

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	25 Jan 2021 17:14:41

US3162006

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:52
User entered 'I'	System	25 Jan 2021 17:14:41

US3162006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	25 Jan 2021 17:15:13

US3162006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '21 Dec 2020'	Tiffany Williams (b) (4)	25 Jan 2021 17:15:13

US3162006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4)	25 Jan 2021 17:15:13

US3162006

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Tiffany Williams (b) (4)	25 Jan 2021 17:15:13

US3162006

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	25 Jan 2021 17:15:25

US3162006

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:52
User entered 'I'	System	25 Jan 2021 17:15:25

US3162006

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	27 Jan 2021 17:49:19

US3162006

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '21 Jan 2021'	Tiffany Williams (b) (4)	27 Jan 2021 17:49:19

US3162006

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4)	27 Jan 2021 17:49:19

US3162006

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Tiffany Williams (b) (4)	27 Jan 2021 17:49:19

US3162006

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	27 Jan 2021 17:49:27

US3162006

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 16:18:52
User entered 'I'	System	27 Jan 2021 17:49:27

US3162006

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	17 Feb 2021 20:57:57

US3162006

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User closed query 'Per GCL Lab Recon: Immuno : Sample dated "15` FEB 2021" is reported under Visit 4 D 209 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in this Visit 4 D 209 Immunogenicity assessment form in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 15:10:36
Query 'Per GCL Lab Recon: Immuno : Sample dated "15` FEB 2021" is reported under Visit 4 D 209 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in this Visit 4 D 209 Immunogenicity assessment form in EDC. Thank you.' answered with 'updated' (Site from DM).	Judith Kirstein (b) (4)	16 Mar 2021 16:13:11
User opened query 'Per GCL Lab Recon: Immuno : Sample dated "15` FEB 2021" is reported under Visit 4 D 209 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in this Visit 4 D 209 Immunogenicity assessment form in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 09:51:21
User entered '15 Feb 2021'	Tiffany Williams (b) (4)	17 Feb 2021 20:57:57

US3162006

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4)	17 Feb 2021 20:57:57

US3162006

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User entered 'VISIT4'	System	17 Feb 2021 20:57:57

US3162006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 18:37:54

US3162006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:37:54

US3162006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:37:54

US3162006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User entered empty.	System	30 Mar 2021 18:37:54

US3162006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:37:54

US3162006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:37:54

US3162006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:37:54

US3162006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:37:54

US3162006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User entered empty.	System	30 Mar 2021 18:37:54

US3162006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:37:54

US3162006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User entered empty.	System	30 Mar 2021 18:37:54

US3162006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:37:54

US3162006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User entered empty.	System	30 Mar 2021 18:37:54

US3162006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:37:54

US3162006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User entered empty.	System	30 Mar 2021 18:37:54

US3162006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05

US3162006

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05

US3162006

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'No (N)'	Tiffany Williams (b) (4)	17 Feb 2021 20:58:07

US3162006

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	Tiffany Williams (b) (4)	17 Feb 2021 20:58:07

US3162006

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	16 Mar 2021 16:12:17
User entered 'No (N)'	Tiffany Williams (b) (4)	10 Mar 2021 00:38:59

US3162006

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '15 Feb 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4)	16 Mar 2021 16:12:17
User entered empty.	Tiffany Williams (b) (4)	10 Mar 2021 00:38:59

US3162006

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '15:41' reason for change: Data Entry Error	Judith Kirstein (b) (4)	16 Mar 2021 16:12:17
User entered empty.	Tiffany Williams (b) (4)	10 Mar 2021 00:38:59

US3162006

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User entered '15 Feb 2021 15:41'	System	16 Mar 2021 16:12:17
User entered empty.	System	10 Mar 2021 00:38:59

US3162006

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	17 Feb 2021 20:58:12

US3162006

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:54:05
User entered 'I'	System	17 Feb 2021 20:58:12

US3162006

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:56
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	23 Mar 2021 18:28:45

US3162006

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:56
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '22 Mar 2021'	Tiffany Williams (b) (4)	23 Mar 2021 18:28:45

US3162006

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:56
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4)	23 Mar 2021 18:28:45

US3162006

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:56
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	Tiffany Williams (b) (4)	23 Mar 2021 18:28:45

US3162006

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:56
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	23 Mar 2021 18:28:51

US3162006

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:27:56
User entered 'I'	System	23 Mar 2021 18:28:51

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:24:55

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Please complete data entry for COVID-19 Severity Assessment. Thank you.' (Site from CRA).	(b) (4), (b) (6)	15 Nov 2020 21:33:18
Query 'Please complete data entry for COVID-19 Severity Assessment. Thank you.' answered with 'DONE' (Site from CRA).	Judith Kirstein (b) (4)	14 Nov 2020 06:40:54
User opened query 'Please complete data entry for COVID-19 Severity Assessment. Thank you.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 00:36:28
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:29:49
User entered '10 Nov 2020'	Judith Kirstein (b) (4)	11 Nov 2020 01:30:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:24:55

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:29:49
User entered '11:17'	Judith Kirstein (b) (4)	11 Nov 2020 01:30:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:24:55

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '10 Nov 2020 11:17'	System	11 Nov 2020 01:30:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:24:55

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:29:49
User entered 'Safety Call (Safety Call)'	Judith Kirstein (b) (4)	11 Nov 2020 01:30:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:24:55

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:29:49
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	11 Nov 2020 01:30:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Day 1 (Day 1)'	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered '9 Nov 2020'	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:53:00
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Per CDM: Assessment Not Done is ticked however there are several Symptoms on this eCRF that have a response. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 09:40:49
Query 'Per CDM: Assessment Not Done is ticked however there are several Symptoms on this eCRF that have a response. Please reconcile or clarify.' answered with 'corrected' (Site from DM).	Judith Kirstein (b) (4)	23 Jan 2021 05:40:07
DataPoint Un-verified.	Judith Kirstein (b) (4)	23 Jan 2021 05:39:48
User entered '0' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Jan 2021 05:39:48
User opened query 'Per CDM: Assessment Not Done is ticked however there are several Symptoms on this eCRF that have a response. Please reconcile or clarify.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 16:01:52
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 17:45:02
DataPoint Un-verified.	Judith Kirstein (b) (4)	18 Jan 2021 05:55:02
User entered '1' reason for change: Data Entry Error	Judith Kirstein (b) (4)	18 Jan 2021 05:55:02
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered '0'	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:53:02
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Per CDM: It appears this form has been completed however the O2 Saturation and Temperature are missing. If these two assessments were not collected, please consider recording these as "Not Done"' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 09:40:51
Query 'Per CDM: It appears this form has been completed however the O2 Saturation and Temperature are missing. If these two assessments were not collected, please consider recording these as "Not Done"' answered with 'done' (Site from DM).	Judith Kirstein (b) (4)	23 Jan 2021 05:40:19
DataPoint Un-verified.	Judith Kirstein (b) (4)	23 Jan 2021 05:39:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4)	23 Jan 2021 05:39:48
User opened query 'Per CDM: It appears this form has been completed however the O2 Saturation and Temperature are missing. If these two assessments were not collected, please consider recording these as "Not Done"' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 16:03:29
User closed query 'Per CDM: It appears that O2 Saturation and temperature are missing. If not collected, please consider recording these as Not Done.' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 16:03:29
Query 'Per CDM: It appears that O2 Saturation and temperature are missing. If not collected, please consider recording these as Not Done.' answered with 'Corrected' (Site from DM).	Judith Kirstein (b) (4)	18 Jan 2021 05:55:17
User opened query 'Per CDM: It appears that O2 Saturation and temperature are missing. If not collected, please consider recording these as Not Done.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:07:28
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '%'	System	23 Jan 2021 05:39:48
User entered empty.	System	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:53:05
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Un-verified.	Judith Kirstein (b) (4)	23 Jan 2021 05:39:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4)	23 Jan 2021 05:39:48
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered empty.	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'Moderate (Moderate)'	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'Severe (Severe)'	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:24:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:33:42

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Day 2 (Day 2)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered '10 Nov 2020'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered '0'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered '99'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '%'	System	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered '96.3' F	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'Mild (Mild)' reason for change: Per Query Resolution	(b) (4), (b) (6)	12 Nov 2020 16:52:18
User entered 'Moderate (Moderate)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006**Folder: Covid-19 Assessment 10 Nov 2020****Form: Symptom Log (2)****Generated On: 09 Jun 2021 15:24:55**[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'Moderate (Moderate)' reason for change: Per Query Resolution	(b) (4), (b) (6)	12 Nov 2020 16:52:18
User entered 'Severe (Severe)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:24:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Day 3 (Day 3)'	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered '0'	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered missing code ND - Not Done.	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '%'	System	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered missing code ND - Not Done.	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'Moderate (Moderate)'	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'Severe (Severe)'	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:24:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:23:43

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Day 4 (Day 4)'	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered '12 Nov 2020'	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered '0'	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered missing code ND - Not Done.	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '%'	System	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered missing code ND - Not Done.	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'Moderate (Moderate)'	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:24:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	12 Nov 2020 23:26:06

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Day 5 (Day 5)'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered '13 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:53
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered '0'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:54
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered '99'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '%'	System	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:56
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered '97.1' F	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:58
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:35:01
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'Moderate (Moderate)'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:35:03
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:35:04
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:35:06
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:35:08
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:35:10
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:35:12
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:35:14
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:35:16
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:35:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:35:20
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:35:21
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:35:24
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:35:26
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:24:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
DataPoint Un-verified.	(b) (4), (b) (6)	14 Nov 2020 00:35:27
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:34:38
User entered 'None (None)'	Judith Kirstein (b) (4)	13 Nov 2020 21:04:00

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Day 6 (Day 6)'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '14 Nov 2020'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '0'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '98'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '%'	System	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '98.2' F	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Moderate (Moderate)'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:24:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	14 Nov 2020 22:34:20

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Day 7 (Day 7)'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '15 Nov 2020'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '0'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '93'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '%'	System	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '97.4' F	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:24:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 04:34:54

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Day 8 (Day 8)'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '16 Nov 2020'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '0'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '99'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '%'	System	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '96.5' F	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:24:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	16 Nov 2020 20:23:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Day 9 (Day 9)'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '17 Nov 2020'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '0'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '99'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '%'	System	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '98.5' F	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:24:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	17 Nov 2020 20:22:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Day 10 (Day 10)'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '18 Nov 2020'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '0'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '98'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '%'	System	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '98.0' F	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:24:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	18 Nov 2020 23:07:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Day 11 (Day 11)'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '19 Nov 2020'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '0'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '100'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '%'	System	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '97.9' F	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:24:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	19 Nov 2020 19:41:28

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Day 12 (Day 12)'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '20 Nov 2020'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '0'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '99'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '%'	System	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '98.1' F	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 15:24:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	20 Nov 2020 19:39:01

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Day 13 (Day 13)'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '21 Nov 2020'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '0'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '98'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '%'	System	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '97.9' F	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 15:24:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	21 Nov 2020 20:23:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Day 14 (Day 14)'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '22 Nov 2020'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '0'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '94'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '%'	System	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '98.7' F	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 15:24:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:10:33

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Day 15 (Day 15)'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '23 Nov 2020'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '0'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '96'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '%'	System	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '98.5' F	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 15:24:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	23 Nov 2020 18:12:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Day 16 (Day 16)'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '24 Nov 2020'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '0'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '95'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '%'	System	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered '97.2' F	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 15:24:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:02:46
User entered 'None (None)'	Judith Kirstein (b) (4)	24 Nov 2020 20:30:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Day 17 (Day 17)'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered '25 Nov 2020'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered '0'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered '96'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '%'	System	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered '98.0' F	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 15:24:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	25 Nov 2020 23:37:48

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Day 18 (Day 18)'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered '26 Nov 2020'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered '0'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered '99'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '%'	System	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered '98.6' F	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'Mild (Mild)'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 15:24:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	26 Nov 2020 17:47:14

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Day 19 (Day 19)'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered '27 Nov 2020'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered '0'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered '98'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered '%'	System	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered '98.8' F	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 15:24:55

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:01:01
User entered 'None (None)'	Judith Kirstein (b) (4)	27 Nov 2020 23:34:18

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:24:55

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User closed query 'Please answer "no" to Generate Next COVID-19 Assessment eCRF within this COVID 19 Assessments Folder. If another COVID-19 assessment needs to be done, you will update this to "yes" and it will populate the next COVID-19 Folder. Thank you.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6)	16 Feb 2021 02:00:59
	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
Query 'Please answer "no" to Generate Next COVID-19 Assessment eCRF within this COVID 19 Assessments Folder. If another COVID-19 assessment needs to be done, you will update this to "yes" and it will populate the next COVID-19 Folder. Thank you.' answered with 'You told me on 05FEB to answer yes to this question in all cases. ' (Site from CRA).	Judith Kirstein (b) (4)	09 Feb 2021 05:46:55
User opened query 'Please answer "no" to Generate Next COVID-19 Assessment eCRF within this COVID 19 Assessments Folder. If another COVID-19 assessment needs to be done, you will update this to "yes" and it will populate the next COVID-19 Folder. Thank you.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	03 Feb 2021 17:08:25
	(b) (4), (b) (6)	14 Nov 2020 00:23:41
User entered '10 Nov 2020'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:24:55

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:23:41
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:24:55

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
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)	17 Nov 2020 11:09:17
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:23:41
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 'Done' (Site from System).	Judith Kirstein (b) (4)	13 Nov 2020 15:39:04
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 15:38:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 15:38:46
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	13 Nov 2020 15:38:46
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 15:38:46
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 01:37:29
User entered empty.	Judith Kirstein (b) (4)	11 Nov 2020 01:37:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:24:55

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:23:41
User entered '10 Nov 2020'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:24:55

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:23:41
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:24:55

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:23:41
User entered empty.	Judith Kirstein (b) (4)	11 Nov 2020 01:37:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:24:55

[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)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:23:41
User entered 'No (N)'	Judith Kirstein (b) (4)	11 Nov 2020 01:37:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:24:55

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:23:41
User entered empty.	Judith Kirstein (b) (4)	11 Nov 2020 01:37:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:24:55

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:23:41
User entered empty.	Judith Kirstein (b) (4)	11 Nov 2020 01:37:29

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:24:55

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User entered 'I'	System	13 Nov 2020 15:38:46

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Thank you for your response, but the question "did the subject have an oxygen saturation SpO2 < or = to 93%? The symptom log notes 93% on Day 7, November 15, 2020. Please update your answer to "yes" and update data entry for the corresponding 3 questions below.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 22:57:05
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	20 Nov 2020 01:05:02
Query 'Thank you for your response, but the question "did the subject have an oxygen saturation SpO2 < or = to 93%? The symptom log notes 93% on Day 7, November 15, 2020. Please update your answer to "yes" and update data entry for the corresponding 3 questions below.' answered with 'The question includes "sea level" but we are 2000 feet above sea level. Also, the subject's oximeter was not working properly and we had to replace it. ' (Site from CRA).	Judith Kirstein (b) (4)	19 Nov 2020 19:28:13
User opened query 'Thank you for your response, but the question "did the subject have an oxygen saturation SpO2 < or = to 93%? The symptom log notes 93% on Day 7, November 15, 2020. Please update your answer to "yes" and update data entry for the corresponding 3 questions below.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:29:20
User closed query 'Please reconcile as Day 7 of symptom log notes 93% O2' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:47:31
Query 'Please reconcile as Day 7 of symptom log notes 93% O2' answered with 'We are not at sea level' (Site from CRA).	Judith Kirstein (b) (4)	19 Nov 2020 16:34:25
User opened query 'Please reconcile as Day 7 of symptom log notes 93% O2' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 05:43:23

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

Did the subject have Oxygen Saturation of $\text{SpO}_2 \leq 93\%$ on room air at sea level?

Audit	User	Time (GMT)
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:04:32
User closed query 'Please complete the Oxygen Saturation questions based on your answer above (from Day 7, Nov 15). ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 17:04:21
Query 'Please complete the Oxygen Saturation questions based on your answer above (from Day 7, Nov 15). ' answered with 'Done' (Site from CRA).	Judith Kirstein (b) (4)	24 Nov 2020 16:17:29
User entered '15 Nov 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	24 Nov 2020 16:17:16
User opened query 'Please complete the Oxygen Saturation questions based on your answer above (from Day 7, Nov 15). ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 22:59:22
Query 'Please complete the Oxygen Saturation questions based on your answer above (from Nov 7). ' canceled (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 22:59:08
User opened query 'Please complete the Oxygen Saturation questions based on your answer above (from Nov 7). ' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 22:58:43
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 22:57:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:04:34
User closed query 'Complete end date.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 17:04:23
Query 'Complete end date.' answered with 'Done' (Site from CRA).	Judith Kirstein (b) (4)	24 Nov 2020 16:17:36
User entered '16 Nov 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	24 Nov 2020 16:17:16
User opened query 'Complete end date.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 22:59:55
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 22:57:09
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

Oxygen Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:04:36
User closed query 'Oxygen Sat is reported at 93%, please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 17:04:29
Query 'Oxygen Sat is reported at 93%, please verify. Thank you.' answered with 'Done' (Site from CRA).	Judith Kirstein (b) (4)	24 Nov 2020 16:17:42
User entered '93' reason for change: Data Entry Error	Judith Kirstein (b) (4)	24 Nov 2020 16:17:16
User opened query 'Oxygen Sat is reported at 93%, please verify. Thank you.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 23:00:21
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 22:57:38
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

Did the subject have Respiratory failure?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User closed query 'Per CDM, 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. Else clarify' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 09:14:33
Query 'Per CDM, 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. Else clarify' answered with 'start and end date entered, per query request ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 22:32:40
User opened query 'Per CDM, 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. Else clarify' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 08:51:58
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:51:14
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Per DM: it appears that 'Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg' is recorded as NO yet there is a record for Diastolic Blood Pressure as 57mmHg in Illness Visit dated 05JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 09:40:23
User closed query 'Per DM: it appears that 'Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg' is recorded as NO yet there is a record for Diastolic Blood Pressure as 54mmHg in Illness Visit dated 26OCT2020. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 09:40:19

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Query 'Per DM: it appears that 'Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg' is recorded as NO yet there is a record for Diastolic Blood Pressure as 57mmHg in Illness Visit dated 05JAN2021. Please review and reconcile.' answered with 'Subject was no longer ill, and she did not have shock at any time during the illness' (Site from DM).	Judith Kirstein (b) (4)	23 Jan 2021 05:42:20
Query 'Per DM: it appears that 'Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg' is recorded as NO yet there is a record for Diastolic Blood Pressure as 54mmHg in Illness Visit dated 26OCT2020. Please review and reconcile.' answered with 'changed' (Site from DM).	Judith Kirstein (b) (4)	23 Jan 2021 05:41:03
DataPoint Un-verified.	Judith Kirstein (b) (4)	23 Jan 2021 05:40:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Jan 2021 05:40:53
User opened query 'Per DM: it appears that 'Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg' is recorded as NO yet there is a record for Diastolic Blood Pressure as 57mmHg in Illness Visit dated 05JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 21:00:11
User opened query 'Per DM: it appears that 'Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg' is recorded as NO yet there is a record for Diastolic Blood Pressure as 54mmHg in Illness Visit dated 26OCT2020. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 20:59:37
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:45:53
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 22:32:16
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 22:32:16
User entered '10 Nov 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	09 Apr 2021 22:32:16
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 00:45:55
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 22:32:16
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 22:32:16
User entered '03 Feb 2021' reason for change: Per Query Resolution	(b) (4), (b) (6)	09 Apr 2021 22:32:16
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 15:24:55

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 22:56:25
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:35:34

US3162006

Folder: Covid-19 Assessment 10 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:24:55

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:00:47
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 17:44:33
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	06 Feb 2021 20:10:50
User entered 'No (N)'	Judith Kirstein (b) (4)	06 Feb 2021 02:29:03

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:24:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User accepted default value 'Day 3 (Day 3)'	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:24:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:38:17
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:24:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:38:17
User entered '12 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:24:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User accepted default value 'Day 5 (Day 5)'	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:24:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:10:01
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 04:35:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 04:35:26
DataPoint Un-verified.	Judith Kirstein (b) (4)	16 Nov 2020 04:35:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	16 Nov 2020 04:35:26
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:38:17
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 15:39:39
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:24:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:10:01
DataPoint Un-verified.	Judith Kirstein (b) (4)	16 Nov 2020 04:35:26
User entered '14 Nov 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	16 Nov 2020 04:35:26
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:38:17
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:24:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User accepted default value 'Day 7 (Day 7)'	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:24:55

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:10:01
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 20:41:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 20:41:31
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 20:41:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 20:41:31
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:38:17
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 15:39:39
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:24:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:10:01
DataPoint Un-verified.	(b) (4), (b) (6)	17 Nov 2020 20:41:31
User entered '16 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	17 Nov 2020 20:41:31
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:38:17
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:24:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User accepted default value 'Day 9 (Day 9)'	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:24:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:10:01
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 20:58:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 20:58:00
DataPoint Un-verified.	Judith Kirstein (b) (4)	18 Nov 2020 20:58:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	18 Nov 2020 20:58:00
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:38:17
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 15:39:39
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:24:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:10:01
DataPoint Un-verified.	Judith Kirstein (b) (4)	18 Nov 2020 20:58:00
User entered '18 Nov 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	18 Nov 2020 20:58:00
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:38:17
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:24:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User accepted default value 'Day 14 (Day 14)'	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:24:55

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:10:01
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 18:12:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 18:12:50
DataPoint Un-verified.	Judith Kirstein (b) (4)	23 Nov 2020 18:12:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Nov 2020 18:12:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:38:17
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 15:39:39
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:24:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:10:01
DataPoint Un-verified.	Judith Kirstein (b) (4)	23 Nov 2020 18:12:50
User entered '23 Nov 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Nov 2020 18:12:50
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:38:17
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:24:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User accepted default value 'Day 21 (Day 21)'	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:24:55

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:09:06
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 04:23:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Dec 2020 04:23:53
DataPoint Un-verified.	Judith Kirstein (b) (4)	02 Dec 2020 04:23:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	02 Dec 2020 04:23:53
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:38:17
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 15:39:39
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:24:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:09:08
DataPoint Un-verified.	Judith Kirstein (b) (4)	02 Dec 2020 04:23:53
User entered '30 Nov 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	02 Dec 2020 04:23:53
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:38:17
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:24:55

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User accepted default value 'Day 28 (Day 28)'	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:24:55

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:15:32
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Dec 2020 07:50:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Dec 2020 07:50:51
DataPoint Un-verified.	Judith Kirstein (b) (4)	08 Dec 2020 07:50:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	08 Dec 2020 07:50:51
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:38:17
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 15:39:39
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:24:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:15:32
DataPoint Un-verified.	Judith Kirstein (b) (4)	08 Dec 2020 07:50:51
User entered '7 Dec 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	08 Dec 2020 07:50:51
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:38:17
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 15:39:39

US3162006

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 07 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit or provide clarification, thank you.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 07:01:58
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 07 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit or provide clarification, thank you.' answered with 'It was collected. The day 28 visit has now been entered' (Site from DM).	Judith Kirstein (b) (4)	18 Dec 2020 04:45:46
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 07 DEC 2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit or provide clarification, thank you.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 08:36:25
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:36:37
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	11 Nov 2020 01:38:25

US3162006

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:36:37
User entered '10 Nov 2020'	Judith Kirstein (b) (4)	11 Nov 2020 01:38:25

US3162006

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

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 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:36:37
User entered 'Clinic (Clinic)'	Judith Kirstein (b) (4)	11 Nov 2020 01:38:25

US3162006

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User entered 'SICKD1'	System	11 Nov 2020 01:38:25

US3162006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:37:38
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	11 Nov 2020 01:39:46

US3162006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:37:38
User entered '10 Nov 2020'	Judith Kirstein (b) (4)	11 Nov 2020 01:39:46

US3162006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:37:38
User entered '14:01'	Judith Kirstein (b) (4)	11 Nov 2020 01:39:46

US3162006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User entered '10 Nov 2020 14:01'	System	11 Nov 2020 01:39:46

US3162006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 19:45:55
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:37:38
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Judith Kirstein (b) (4)	11 Nov 2020 01:41:52
answered with 'NCS, not AE' (Site from System).		
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Nov 2020 01:39:46
User entered '96.3' F	Judith Kirstein (b) (4)	11 Nov 2020 01:39:46

US3162006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:37:38
User entered 'Oral (Oral)'	Judith Kirstein (b) (4)	11 Nov 2020 01:39:46

US3162006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:37:38
User entered empty.	Judith Kirstein (b) (4)	11 Nov 2020 01:39:46

US3162006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:37:38
User entered '61'	Judith Kirstein (b) (4)	11 Nov 2020 01:39:46

US3162006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User entered 'bpm'	System	11 Nov 2020 01:39:46

US3162006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:37:38
User entered '13'	Judith Kirstein (b) (4)	11 Nov 2020 01:39:46

US3162006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User entered 'breaths/min'	System	11 Nov 2020 01:39:46

US3162006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:37:38
User entered '128'	Judith Kirstein (b) (4)	11 Nov 2020 01:39:46

US3162006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User entered 'mmHg'	System	11 Nov 2020 01:39:46

US3162006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:37:38
User entered '62'	Judith Kirstein (b) (4)	11 Nov 2020 01:39:46

US3162006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User entered 'mmHg'	System	11 Nov 2020 01:39:46

US3162006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53

US3162006

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53

US3162006

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:37:52
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	11 Nov 2020 01:39:59

US3162006

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:37:52
User entered '10 Nov 2020'	Judith Kirstein (b) (4)	11 Nov 2020 01:39:59

US3162006

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:24:55

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:38:03
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	11 Nov 2020 01:40:15

US3162006

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:24:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:40:53
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:38:03
User entered '10 Nov 2020'	Judith Kirstein (b) (4)	11 Nov 2020 01:40:15

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:04:24
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	17 Dec 2020 21:56:40

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:04:24
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re Query: it appears PPD central lab has a SARS-CoV-2 serum sample dated 07 DEC 2020 as a Convalescence Visit Day 28, but there is no record in EDC with this date. Please reconcile and update the data else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 16:16:27
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re Query: it appears PPD central lab has a SARS-CoV-2 serum sample dated 07 DEC 2020 as a Convalescence Visit Day 28, but there is no record in EDC with this date. Please reconcile and update the data else clarify.' answered with 'That has been updated' (Site from DM).	Judith Kirstein (b) (4)	22 Dec 2020 00:41:24
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re Query: it appears PPD central lab has a SARS-CoV-2 serum sample dated 07 DEC 2020 as a Convalescence Visit Day 28, but there is no record in EDC with this date. Please reconcile and update the data else clarify.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 07:53:41
User entered '7 Dec 2020'	Judith Kirstein (b) (4)	17 Dec 2020 21:56:40

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:04:24
User entered 'Clinic (Clinic)'	Judith Kirstein (b) (4)	17 Dec 2020 21:56:40

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User entered 'SICKD28'	System	17 Dec 2020 21:56:40

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:05:08
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	22 Dec 2020 00:14:34

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:05:08
User entered '7 Dec 2020'	Tiffany Williams (b) (4)	22 Dec 2020 00:14:34

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:05:08
User entered '14:48'	Tiffany Williams (b) (4)	22 Dec 2020 00:14:34

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User entered '7 Dec 2020 14:48'	System	22 Dec 2020 00:14:34

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:05:08
User entered '98.1' F	Tiffany Williams (b) (4)	22 Dec 2020 00:14:34

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:05:08
User entered 'Oral (Oral)'	Tiffany Williams (b) (4)	22 Dec 2020 00:14:34

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:05:08
User entered empty.	Tiffany Williams (b) (4)	22 Dec 2020 00:14:34

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:05:08
User entered '63'	Tiffany Williams (b) (4)	22 Dec 2020 00:14:34

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User entered 'bpm'	System	22 Dec 2020 00:14:34

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:05:08
User entered '12'	Tiffany Williams (b) (4)	22 Dec 2020 00:14:34

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User entered 'breaths/min'	System	22 Dec 2020 00:14:34

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:05:08
User entered '126'	Tiffany Williams (b) (4)	22 Dec 2020 00:14:34

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User entered 'mmHg'	System	22 Dec 2020 00:14:34

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:05:08
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	28 Dec 2020 03:00:40
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS, not AE' (Site from System).	Judith Kirstein (b) (4)	22 Dec 2020 00:15:15
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		22 Dec 2020 00:14:34
User entered '57'	Tiffany Williams (b) (4)	22 Dec 2020 00:14:34

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User entered 'mmHg'	System	22 Dec 2020 00:14:34

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:05:20
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	22 Dec 2020 00:15:25

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:05:20
User entered '7 Dec 2020'	Tiffany Williams (b) (4)	22 Dec 2020 00:15:25

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:24:55

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:05:28
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	22 Dec 2020 00:15:40

US3162006

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 15:24:55

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:35:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 18:05:28
User entered '7 Dec 2020'	Tiffany Williams (b) (4)	22 Dec 2020 00:15:40

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	04 Feb 2021 00:05:53

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '3 Feb 2021'	Tiffany Williams (b) (4)	04 Feb 2021 00:05:53

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[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 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4)	04 Feb 2021 00:05:53

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'UNBLND_DECIDE'	System	04 Feb 2021 00:05:53

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:24:55

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '3 Feb 2021'	Tiffany Williams (b) (4)	04 Feb 2021 00:11:00

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:24:55

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:02:04

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:24:55

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	04 Feb 2021 00:11:00

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:24:55

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
	(b) (6) la1)	
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
	(b) (6)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:02:04

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:24:55

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '3 Feb 2021'	Tiffany Williams (b) (4)	04 Feb 2021 00:11:00

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:24:55

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4)	04 Feb 2021 00:11:00

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:24:55

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4)	04 Feb 2021 00:11:00

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:24:55

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4)	04 Feb 2021 00:11:00

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:24:55

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	04 Feb 2021 00:11:00

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:24:55

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered '1'	System	04 Feb 2021 00:11:00

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:24:55

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'I'	System	04 Feb 2021 00:11:00

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:24:55

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '61' in	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:24:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '138.2' lb	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:24:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered '26.16726'	System	04 Feb 2021 22:56:15
DataPoint set to visible.	System	04 Feb 2021 00:11:00

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:24:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '61' in	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:24:55

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '138.2' lb	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:24:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered '26.16726'	System	04 Feb 2021 22:56:15
DataPoint set to visible.	System	04 Feb 2021 00:11:00

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Williams (b) (4) (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '3 Feb 2021'	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '15:30'	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered '3 Feb 2021 15:30'	System	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '98.7' F	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Oral (Oral)'	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '72'	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'bpm'	System	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '15'	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'breaths/min'	System	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '127'	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'mmHg'	System	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '80'	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'mmHg'	System	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:24:55

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '61' in	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:24:55

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '138.2' lb	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:24:55

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered '26.16726'	System	04 Feb 2021 22:56:15
DataPoint set to visible.	System	04 Feb 2021 00:11:00

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Williams (b) (4) (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '3 Feb 2021'	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '16:30'	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered '3 Feb 2021 16:30'	System	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '98.2' F	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Oral (Oral)'	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '84'	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'bpm'	System	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '14'	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'breaths/min'	System	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '140'	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'mmHg'	System	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '88'	Tiffany Williams (b) (4)	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'mmHg'	System	04 Feb 2021 22:56:15

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Tiffany Williams (b) (4)	04 Feb 2021 22:56:43

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Tiffany Williams (b) (4)	04 Feb 2021 22:56:43

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	04 Feb 2021 00:11:28

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Tiffany Williams (b) (4)	04 Feb 2021 00:11:28

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Tiffany Williams (b) (4)	04 Feb 2021 00:11:28

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'mRNA-1273'	System	04 Feb 2021 00:11:28
DataPoint set to visible.	System	04 Feb 2021 00:11:00

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '3 Feb 2021'	Tiffany Williams (b) (4)	04 Feb 2021 00:11:28

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '15:55'	Tiffany Williams (b) (4)	04 Feb 2021 00:11:28

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered '3 Feb 2021 15:55'	System	04 Feb 2021 00:11:28

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Left Arm (LEFT ARM)'	Tiffany Williams (b) (4)	04 Feb 2021 00:11:28

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'ONCE'	System	04 Feb 2021 00:11:28

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'INTRAMUSCULAR'	System	04 Feb 2021 00:11:28

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	04 Feb 2021 22:57:04

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	04 Feb 2021 22:57:20
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		04 Feb 2021 22:57:20
User entered '3 Feb 2021' reason for change: New Information	Tiffany Williams (b) (4)	04 Feb 2021 22:57:20
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	04 Feb 2021 22:57:04
User entered '4 Feb 2021'	Tiffany Williams (b) (4)	04 Feb 2021 22:57:04

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '15:40'	Tiffany Williams (b) (4)	04 Feb 2021 22:57:04

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered '3 Feb 2021 15:40'	System	04 Feb 2021 22:57:20
User entered '4 Feb 2021 15:40'	System	04 Feb 2021 22:57:04

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:24:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	04 Feb 2021 22:57:50

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:24:55

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '3 Feb 2021'	Tiffany Williams (b) (4)	04 Feb 2021 22:57:50

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:24:55

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '15:43'	Tiffany Williams (b) (4)	04 Feb 2021 22:57:50

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:24:55

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered '3 Feb 2021 15:43'	System	04 Feb 2021 22:57:50

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	04 Feb 2021 00:11:37

US3162006

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'I'	System	04 Feb 2021 00:11:37

US3162006

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	05 Mar 2021 17:08:58

US3162006

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '10 Feb 2021'	Tiffany Williams (b) (4)	05 Mar 2021 17:08:58

US3162006

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4)	05 Mar 2021 17:08:58

US3162006

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	Tiffany Williams (b) (4)	05 Mar 2021 17:08:58

US3162006

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	05 Mar 2021 17:09:10

US3162006

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'I'	System	05 Mar 2021 17:09:10

US3162006

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered '1'	System	05 Mar 2021 17:09:10
DataPoint set to visible.	System	05 Mar 2021 17:09:10

US3162006

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	05 Mar 2021 17:10:17

US3162006

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '11 Mar 2021' reason for change: New Information	Tiffany Williams (b) (4)	11 Mar 2021 19:41:44
User entered '3 Mar 2021'	Tiffany Williams (b) (4)	05 Mar 2021 17:10:17

US3162006

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[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 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4)	05 Mar 2021 17:10:17

US3162006

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'OLD29'	System	05 Mar 2021 17:10:17

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Williams (b) (4) (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Mar 2021 16:09:20
User entered '11 Mar 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4)	16 Mar 2021 16:09:20
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	11 Mar 2021 19:41:44
User entered '3 Mar 2021'	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '10:15' reason for change: Data Entry Error	Judith Kirstein (b) (4)	16 Mar 2021 16:09:20
User entered '13:20'	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered '11 Mar 2021 10:15'	System	16 Mar 2021 16:09:20
User entered '3 Mar 2021 13:20'	System	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	17 Mar 2021 13:57:08
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Judith Kirstein (b) (4)	16 Mar 2021 16:09:34
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Mar 2021 16:09:20
User entered '96.2' F reason for change: Data Entry Error	Judith Kirstein (b) (4)	16 Mar 2021 16:09:20
User entered '97.1' F	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Oral (Oral)'	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '68' reason for change: Data Entry Error	Judith Kirstein (b) (4)	16 Mar 2021 16:09:20
User entered '60'	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'bpm'	System	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '15'	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'breaths/min'	System	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '117' reason for change: Data Entry Error	Judith Kirstein (b) (4)	16 Mar 2021 16:09:20
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	09 Mar 2021 03:17:50
Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'GRADE 4 - PER SOURCE SUBJECT WAS SENT TO PCP OFFICE-AE WAS REPORTED ' (Site from System).	Tiffany Williams (b) (4)	05 Mar 2021 17:17:10
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	05 Mar 2021 17:15:56
User entered '211'	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'mmHg'	System	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '72' reason for change: Data Entry Error	Judith Kirstein (b) (4)	16 Mar 2021 16:09:20
User entered '99'	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:24:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'mmHg'	System	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Williams (b) (4) (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'No (N)'	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered empty.	System	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered empty.	System	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered empty.	System	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered empty.	System	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	Tiffany Williams (b) (4)	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:24:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered empty.	System	05 Mar 2021 17:15:56

US3162006

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'No (N)'	Tiffany Williams (b) (4)	05 Mar 2021 17:17:23

US3162006

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	Tiffany Williams (b) (4)	05 Mar 2021 17:17:23

US3162006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Yes (Y)' reason for change: New Information	Tiffany Williams (b) (4)	11 Mar 2021 19:44:15
User entered 'No (N)'	Tiffany Williams (b) (4)	05 Mar 2021 17:18:24

US3162006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty; reason for change New Information	Tiffany Williams (b) (4)	11 Mar 2021 19:44:15
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	Tiffany Williams (b) (4)	05 Mar 2021 17:18:24

US3162006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty; reason for change New Information	Tiffany Williams (b) (4)	11 Mar 2021 19:44:15
User entered 'PHYSICIAN DECISION'	Tiffany Williams (b) (4)	05 Mar 2021 17:18:24

US3162006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'mRNA-1273'	System	11 Mar 2021 19:44:15
User entered empty.	System	05 Mar 2021 17:18:24
DataPoint set to visible.	System	05 Mar 2021 17:09:10

US3162006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '11 Mar 2021' reason for change: New Information	Tiffany Williams (b) (4)	11 Mar 2021 19:44:15
User entered empty.	Tiffany Williams (b) (4)	05 Mar 2021 17:18:24

US3162006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '11:34' reason for change: New Information	Tiffany Williams (b) (4)	11 Mar 2021 19:44:15
User entered empty.	Tiffany Williams (b) (4)	05 Mar 2021 17:18:24

US3162006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered '11 Mar 2021 11:34'	System	11 Mar 2021 19:44:15
User entered empty.	System	05 Mar 2021 17:18:24

US3162006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Left Arm (LEFT ARM)' reason for change: New Information	Tiffany Williams (b) (4)	11 Mar 2021 19:44:15
User entered empty.	Tiffany Williams (b) (4)	05 Mar 2021 17:18:24

US3162006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'ONCE'	System	11 Mar 2021 19:44:15
User entered empty.	System	05 Mar 2021 17:18:24

US3162006

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:24:55

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'INTRAMUSCULAR'	System	11 Mar 2021 19:44:15
User entered empty.	System	05 Mar 2021 17:18:24

US3162006

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	05 Mar 2021 17:18:32

US3162006

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'I'	System	05 Mar 2021 17:18:32

US3162006

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	19 Mar 2021 22:02:23

US3162006

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '18 Mar 2021'	Tiffany Williams (b) (4)	19 Mar 2021 22:02:23

US3162006

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4)	19 Mar 2021 22:02:23

US3162006

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:24:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	Tiffany Williams (b) (4)	19 Mar 2021 22:02:23

US3162006

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	19 Mar 2021 22:02:30

US3162006

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:24:55

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:51:28
User entered 'I'	System	19 Mar 2021 22:02:30

US3162006

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 22:12:57

US3162006

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '8 Apr 2021'	(b) (4), (b) (6)	08 Apr 2021 22:12:57

US3162006

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Apr 2021 22:12:57

US3162006

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:24:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	08 Apr 2021 22:12:57

US3162006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 22:13:15

US3162006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6) [REDACTED]	08 Apr 2021 22:13:15

US3162006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 22:13:15

US3162006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 22:13:15

US3162006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 22:13:15

US3162006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 22:13:15

US3162006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 22:13:15

US3162006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 22:13:15

US3162006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 22:13:15

US3162006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6) [REDACTED]	08 Apr 2021 22:13:15

US3162006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 22:13:15

US3162006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6) [REDACTED]	08 Apr 2021 22:13:15

US3162006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 22:13:15

US3162006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 22:13:15

US3162006

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:24:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 22:13:15

US3162006

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'No (N)'	(b) (4), (b) (6)	08 Apr 2021 22:13:32

US3162006

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:24:55

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	08 Apr 2021 22:13:32

US3162006

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Apr 2021 22:14:06

US3162006

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '8 Apr 2021'	(b) (4), (b) (6)	08 Apr 2021 22:14:06

US3162006

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '10:12'	(b) (4), (b) (6)	08 Apr 2021 22:14:06

US3162006

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:24:55

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '8 Apr 2021 10:12'	System	08 Apr 2021 22:14:06

US3162006

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:24:55

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:30:59
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 16:56:53
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:47:56

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:35:26
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:38:54
User entered	(b) (4), (b) (6)	16 Nov 2020 13:38:49
'USA-US074-2020-mRNA-1273-P301000008'		

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 21:38:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	23 Nov 2020 21:38:16
Data point term sent to Coder	System	23 Nov 2020 20:59:31
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.	Coder Import (b) (4)	23 Nov 2020 20:59:20
' canceled (Site from System).	(b) (4)	
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.	Coder Import (b) (4)	23 Nov 2020 12:24:20
' (Site from System).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 15:38:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 15:38:45
	(b) (4)	
Data point term sent to Coder	System	13 Nov 2020 15:38:14
Coding entries removed.	Judith Kirstein (b) (4)	13 Nov 2020 15:37:47
User entered 'SYMPTOMATIC COVID-19' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 15:37:47
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection NOS - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 17:05:57
	(b) (4)	

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	12 Nov 2020 17:05:57
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	12 Nov 2020 17:05:04
User entered 'Acute viral infection, unspecified'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 15:37:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 15:37:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 15:37:47
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 17:04:03
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '9 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:09:06
DataPoint Un-verified.	Judith Kirstein (b) (4)	27 Nov 2020 23:35:11
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	27 Nov 2020 23:35:11
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:09:08
DataPoint Un-verified.	Judith Kirstein (b) (4)	27 Nov 2020 23:35:11
User entered '27 Nov 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	27 Nov 2020 23:35:11
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. (COVID 19 event)' canceled (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 20:37:30
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. (COVID 19 event)' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:39:16
User entered empty.	System	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
	(b) (4), (b) (6)	19 Nov 2020 12:13:17
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:24:46
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' answered with 'Changed per query' (Site from DM). DataPoint Un-verified.	Judith Kirstein (b) (4)	18 Nov 2020 20:34:28
	Judith Kirstein (b) (4)	18 Nov 2020 20:34:03
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	18 Nov 2020 20:34:03
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 06:32:21
	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:24:49
DataPoint Un-verified.	Judith Kirstein (b) (4)	18 Nov 2020 20:34:03
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	18 Nov 2020 20:34:03
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 02:38:05
DataPoint Un-verified.	Judith Kirstein (b) (4)	19 Nov 2020 23:32:54
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	19 Nov 2020 23:32:54
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'None (NONE)'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:00:56
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. (COVID 19 event) ' (Site from Safety). Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. (COVID 19 event) ' answered with 'Resolved 27Nov2020' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 14:41:02
DataPoint Un-verified.	Judith Kirstein (b) (4)	27 Nov 2020 23:35:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	27 Nov 2020 23:35:11
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. (COVID 19 event) ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:40:13
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:30:44
User closed query 'While you provided a narrative for the SAE that occurred, the COVID-19 + result also requires a narrative here. Please ensure the eSource and EDC are updated. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 16:30:41
Query 'While you provided a narrative for the SAE that occurred, the COVID-19 + result also requires a narrative here. Please ensure the eSource and EDC are updated. Thank you.' answered with 'Done' (Site from CRA).	Judith Kirstein (b) (4)	10 Dec 2020 04:13:24
DataPoint Un-verified.	Judith Kirstein (b) (4)	10 Dec 2020 04:13:04
User entered 'Subject had onset of Covid symptoms on 9Nov20, had illness visit on 10Nov20, was admitted to hospital on 11Nov20 after ER visit showing Covid and acute renal failure. The renal failure was thought to be due in large part to her taking hydrochlorothiazide, and this medication was stopped. She was not on oxygen during her overnight hospitalization, and she was treated with hydration but no medications specifically for Covid. After discharge, she had an uneventful course, had one telemedicine visit with her PCP and fully recovered.,' reason for change: Data Entry Error	Judith Kirstein (b) (4)	10 Dec 2020 04:13:04
User opened query 'While you provided a narrative for the SAE that occurred, the COVID-19 + result also requires a narrative here. Please ensure the eSource and EDC are updated. Thank you.' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 17:51:07
User closed query 'PV Query: As the event occurred after the second dose of the study drug, please update the action taken with study drug due to the event of COVID-19 from none to not applicable. (COVID 19 event) ' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:38:50

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 22:38:45
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'sent to email ' (Site from Safety).	Jared Bradshaw (b) (4)	20 Nov 2020 03:54:37
Query 'PV Query: As the event occurred after the second dose of the study drug, please update the action taken with study drug due to the event of COVID-19 from none to not applicable. (COVID 19 event) ' answered with 'Changed' (Site from Safety).	Judith Kirstein (b) (4)	19 Nov 2020 23:33:10
User opened query 'PV Query: As the event occurred after the second dose of the study drug, please update the action taken with study drug due to the event of COVID-19 from none to not applicable. (COVID 19 event) ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:40:00
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 22:39:35
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:24:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 17:04:03

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:33:28
User entered	System	13 Nov 2020 15:33:23
'USA-US074-2020-mRNA-1273-P301000008'		
User entered 'New'	(b) (4), (b) (6)	13 Nov 2020 15:33:23

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Acute kidney injury, LLT: Acute renal failure - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 18:09:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	13 Nov 2020 18:09:48
Data point term sent to Coder	System	13 Nov 2020 18:08:35
Coding entries removed.	Judith Kirstein (b) (4)	13 Nov 2020 18:08:15
	(b) (4)	
User entered 'ACUTE RENAL FAILURE' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 18:08:15
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Asthenia, LLT: Weakness - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 23:22:36
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 23:22:36
	(b) (4)	
Data point term sent to Coder	System	12 Nov 2020 23:20:38
User entered 'EXTREME WEAKNESS'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15
	(b) (4)	

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	14 Nov 2020 01:33:01
User entered 'No (N)'	Judith Kirstein (b) (4) [REDACTED] [REDACTED]	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'No (N)'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	13 Nov 2020 18:08:15
User entered empty; reason for change Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 18:08:15
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	12 Nov 2020 23:20:15
User entered '10:00'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 18:08:15
User entered '11 Nov 2020 10:00'	System	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'No (N)'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '12 Nov 2020'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	13 Nov 2020 18:08:15
User entered empty; reason for change Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 18:08:15
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	12 Nov 2020 23:20:15
User entered '08:00'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 18:08:15
User entered '12 Nov 2020 08:00'	System	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 18:08:15
User entered 'Grade 3/Severe (Grade 3/Severe)'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	14 Nov 2020 01:33:01
User entered '0'	Judith Kirstein (b) (4) [REDACTED] [REDACTED]	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'I'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '12 Nov 2020'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	14 Nov 2020 01:33:01
User entered 'No (N)'	Judith Kirstein (b) (4) [REDACTED] [REDACTED]	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	14 Nov 2020 01:33:01
User entered '0'	Judith Kirstein (b) (4) [REDACTED] [REDACTED]	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	14 Nov 2020 01:33:01
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) [REDACTED] [REDACTED]	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:01:36
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Un-verified.	Judith Kirstein (b) (4)	17 Dec 2020 21:53:21
User entered '0' reason for change: Data Entry Error	Judith Kirstein (b) (4)	17 Dec 2020 21:53:21
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '1'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 18:01:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Un-verified.	Judith Kirstein (b) (4)	17 Dec 2020 21:53:21
User entered '1' reason for change: Data Entry Error	Judith Kirstein (b) (4)	17 Dec 2020 21:53:21
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	14 Nov 2020 01:33:01
User entered empty.	Judith Kirstein (b) (4) [REDACTED] [REDACTED]	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'SUBJECT HAD ONSET OF COVID SYMPTOMS ON 09NOV20 AND WAS SEEN FOR ILLNESS VISIT ON 10NOV20. ON 11NOV20, AT 1000, SHE WAS LIGHTHEADED AND TOO WEAK TO STAND UP, AND WAS TAKEN TO HOSPITAL ER. COVID PCR TEST WAS POSITIVE THERE, AND SHE WAS FOUND TO HAVE ACUTE RENAL FAILURE WITH BUN 37 AND CREATININE 2.2. SHE WAS ADMITTED DUE TO THAT DIAGNOSIS. WE LEARNED OF HER ADMISSION ON 12NOV20, AND SHE WAS DISCHARGED THAT DAY. (12NOV2020). ADDENDUM ON 13NOV2020: RECEIVED MEDICAL RECORDS SHOWING THAT ADMITTING DIAGNOSIS WAS ACUTE RENAL FAILURE. DISCHARGE DIAGNOSES INDICATE "ASYMPTOMATIC COVID" BUT SUBJECT HAD A BAD COUGH AND WAS TREATED WITH ZITHROMAX, DEXAMETHASONE AND ROCEPHIN, SO THAT DIAGNOSIS SHOULD BE SYMPTOMATIC COVID-19. SHE ALSO HAD HYPONATREMIA (129) WHICH RESOLVED AFTER HYDRATION WITH NORMAL SALINE. SHE NEVER NEEDED OXYGEN (ALL O2 SATURATIONS WERE 93 OR GREATER), AND HER TWO CHEST XRAYS WERE NORMAL. HER PHYSICIAN ATTRIBUTED HER RENAL FAILURE TO HYDROCHLOROTHIAZIDE AND CONFERRED WITH HER PCP, THEN STOPPED THAT MEDICATION. THE FOLLOWING DAY, HER CREATININE WAS 1.2 AND BUN 27.'	Judith Kirstein (b) (4)	14 Nov 2020 00:20:48
reason for change: Data Entry Error		

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAD ONSET OF COVID SYMPTOMS ON 09NOV20 AND WAS SEEN FOR ILLNESS VISIT ON 10NOV20. ON 11NOV20, AT 1000, SHE WAS TOO WEAK TO STAND UP, AND WAS TAKEN TO HOSPITAL ER. COVID TEST WAS POSITIVE THERE, AND SHE WAS ADMITTED. WE LEARNED THAT TODAY, AND SHE WAS DISCHARGED TODAY (12NOV2020). ADDENDUM ON 13NOV2020: RECEIVED MEDICAL RECORDS SHOWING THAT ADMITTING DIAGNOSIS WAS ACUTE RENAL FAILURE. RECORD INDICATES "ASYMPTOMATIC COVID" BUT SUBJECT HAD A BAD COUGH AND WAS TREATED WITH ZITHROMAX, DEXAMETHASONE AND ROCEPHIN, SO THAT DIAGNOSIS SHOULD BE SYMPTOMATIC COVID-19.' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 18:08:15
User entered 'Subject had onset of Covid symptoms on 09Nov20 and was seen for illness visit on 10Nov20. On 11Nov20, at 1000, she was too weak to stand up, and was taken to hospital ER. Covid test was positive there, and she was admitted. We learned that today, and she was discharged today.'	Judith Kirstein (b) (4)	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:24:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Nov 2020 23:20:15

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User closed query 'Per Progress notes on 10 Nov 2020, the subject fell in the parking lot. This is an AE and needs to be added to your AE log and entered into EDC. Please update accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 01:31:31
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 00:16:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 00:16:37
Data point term sent to Coder	System	13 Nov 2020 21:26:16
Query 'Per Progress notes on 10 Nov 2020, the subject fell in the parking lot. This is an AE and needs to be added to your AE log and entered into EDC. Please update accordingly. Thank you.' answered with 'ADDED' (Site from CRA).	Judith Kirstein (b) (4)	13 Nov 2020 21:25:44
Coding entries removed.	Judith Kirstein (b) (4)	13 Nov 2020 21:25:29
User entered 'FALL IN PARKING LOT' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 21:25:29
User opened query 'Per Progress notes on 10 Nov 2020, the subject fell in the parking lot. This is an AE and needs to be added to your AE log and entered into EDC. Please update accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 21:05:01
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral infection NOS - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 18:56:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 18:56:48
Data point term sent to Coder	System	13 Nov 2020 18:56:03

PRODUCTION RELEASE (v12.003
EAB) (1725)

2657 of 3607

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Acute viral infection, unspecified'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 21:25:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 21:25:29
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 21:25:29
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 18:55:33
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '10 Nov 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 21:25:29
User entered '9 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User entered empty.	System	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 21:25:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '10 Nov 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 21:25:29
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User entered empty.	System	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 21:25:29
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 12:14:26
	(b) (4), (b) (6)	18 Nov 2020 22:25:32
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' answered with 'Changed per query' (Site from DM). DataPoint Un-verified.	Judith Kirstein (b) (4)	18 Nov 2020 20:33:23
	Judith Kirstein (b) (4)	18 Nov 2020 20:33:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	18 Nov 2020 20:33:06
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 06:32:46
	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:25:36
DataPoint Un-verified.	Judith Kirstein (b) (4)	18 Nov 2020 20:33:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	18 Nov 2020 20:33:06
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'None (NONE)'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	21 Nov 2020 20:20:54
DataPoint Un-verified.	Judith Kirstein (b) (4)	21 Nov 2020 20:20:54
User entered '1' reason for change: Data Entry Error	Judith Kirstein (b) (4)	21 Nov 2020 20:20:54
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	21 Nov 2020 20:20:46
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:22:57
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Corrected' (Site from DM).	Judith Kirstein (b) (4)	21 Nov 2020 20:21:04
DataPoint Un-verified.	Judith Kirstein (b) (4)	21 Nov 2020 20:20:46
User entered '0' reason for change: Data Entry Error	Judith Kirstein (b) (4)	21 Nov 2020 20:20:46
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 13:15:04
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 21:25:29
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User entered '0'	System	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:12
User entered 'I'	System	13 Nov 2020 18:55:33

US3162006

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:24:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 14:12:12

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 14:13:07

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 23:14:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 23:14:35
Data point term sent to Coder	System	13 Nov 2020 23:13:26
User entered 'HYPONATREMIA'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User entered empty.	System	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '12 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User entered empty.	System	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Grade 1/Mild (Grade 1/Mild)'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:23:39
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Normal saline' (Site from DM).	Judith Kirstein (b) (4)	21 Nov 2020 20:21:27
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 13:15:21
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'I'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered '0'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:01
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User entered '0'	System	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:13:07
User entered 'I'	System	13 Nov 2020 23:13:23

US3162006

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:24:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 14:13:07

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 14:12:37

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:48:31
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Lightheadedness - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 21:43:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 21:43:53
Data point term sent to Coder	System	14 Nov 2020 21:43:16
Coding entries removed.	Judith Kirstein (b) (4)	14 Nov 2020 21:43:00
User entered 'LIGHTHEADEDNESS' reason for change: Data Entry Error	Judith Kirstein (b) (4)	14 Nov 2020 21:43:00
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Vertigo, LLT: Vertigo - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 06:40:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 06:40:44
Data point term sent to Coder	System	14 Nov 2020 06:40:01
User entered 'VERTIGO'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:48:33
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:48:35
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:48:37
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:48:38
User entered '10 Nov 2020'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:48:40
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User entered empty.	System	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:48:42
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:48:43
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:48:44
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User entered empty.	System	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:26:50
User closed query 'Source documents note the grade as 4, please verify which is correct and update EDC or eSource as applicable. Thank you.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 22:26:47
Query 'Source documents note the grade as 4, please verify which is correct and update EDC or eSource as applicable. Thank you.' answered with 'Source will be updated' (Site from CRA).	Judith Kirstein (b) (4)	18 Nov 2020 01:12:57
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	18 Nov 2020 01:12:39
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	18 Nov 2020 01:10:55
User opened query 'Source documents note the grade as 4, please verify which is correct and update EDC or eSource as applicable. Thank you.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 21:44:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	18 Nov 2020 01:12:39
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	18 Nov 2020 01:12:39
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	18 Nov 2020 01:10:55
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:48:47
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:48:49
User entered '0'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:48:50
User entered '0'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:48:52
User entered '0'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:48:53
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:48:55
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:48:57
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:48:59
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:49:00
User entered '0'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:49:15
User entered '0'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:49:17
User entered '0'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:49:19
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:49:20
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:49:22
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:49:25
User entered '0'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:49:27
User entered 'I'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:49:29
User entered '0'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:49:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:49:34
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:49:36
User entered 'SUBJECT COMPLAINED OF FEELING "WOOZY" ON 10NOV20 WITH WORSENING ON 11NOV20. WAS TREATED WITH MECLIZINE IN ER ON 11NOV20 AND IT SUBSEQUENTLY RESOLVED. ON 14NOV20, SUBJECT STATED SHE NEVER HAD VERTIGO, JUST LIGHTHEADEDNESS, SO TERM WAS UPDATED. HOSPITAL RECORDS RECEIVED 13NOV20 STATE SHE NEVER LOST CONSCIOUSNESS, SO TERM UPDATED TO LIGHTHEADEDNESS' reason for change: Data Entry Error	Judith Kirstein (b) (4)	14 Nov 2020 21:54:35
User entered 'SUBJECT COMPLAINED OF FEELING "WOOZY" ON 10NOV20 WITH WORSENING ON 11NOV20. WAS TREATED WITH MECLIZINE IN ER ON 11NOV20 AND IT SUBSEQUENTLY RESOLVED. ON 14NOV20, SUBJECT STATED SHE NEVER HAD VERTIGO, JUST LIGHTHEADEDNESS, SO TERM WAS UPDATED.' reason for change: Data Entry Error	Judith Kirstein (b) (4)	14 Nov 2020 21:43:00
User entered 'SUBJECT COMPLAINED OF FEELING "WOOZY" ON 10NOV20 WITH WORSENING ON 11NOV20. WAS TREATED WITH MECLIZINE IN ER ON 11NOV20 AND IT SUBSEQUENTLY RESOLVED'	Judith Kirstein (b) (4)	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User entered '0'	System	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:12:37
User entered 'I'	System	14 Nov 2020 06:39:03

US3162006

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:24:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 14:12:37

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	30 Apr 2021 14:11:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Lightheadedness - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 19:45:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 19:45:02
Data point term sent to Coder	System	19 Nov 2020 19:44:19
User entered 'Lightheadedness'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered 'No (N)'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered 'No (N)'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered '19 Nov 2020'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered empty.	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User entered empty.	System	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	20 Nov 2020 19:36:43
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered '19 Nov 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	20 Nov 2020 19:36:43
User entered empty.	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered empty.	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User entered empty.	System	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered 'No (N)'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered '0'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered '0'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered '0'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered empty.	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered empty.	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered empty.	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered empty.	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered '0'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered '0'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered '0'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered 'I'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered '0'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered '0'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	20 Nov 2020 19:36:43
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered empty.	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:07:52
User entered empty.	Judith Kirstein (b) (4)	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User entered '0'	System	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32
User entered 'I'	System	19 Nov 2020 19:43:32

US3162006

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:24:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:11:32

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:46
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of GASTRITIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 05:35:44
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Gastritis (excl infective), PT: Gastritis, LLT: Gastritis aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Mar 2021 19:33:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Mar 2021 19:33:29
Data point term sent to Coder	System	21 Mar 2021 19:33:25
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of GASTRITIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Judith Kirstein (b) (4)	21 Mar 2021 19:33:16
Coding entries removed.	Judith Kirstein (b) (4)	21 Mar 2021 19:33:07
Signature has been broken.	Judith Kirstein (b) (4)	21 Mar 2021 19:33:07
User entered 'worsening of GASTRITIS' reason for change: Data Entry Error	Judith Kirstein (b) (4)	21 Mar 2021 19:33:07
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of GASTRITIS. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 06:53:27

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Gastritis (excl infective), PT: Gastritis, LLT: Gastritis - version MedDRA\\23.0.	Coder Import (b) (4)	07 Mar 2021 04:25:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Mar 2021 04:25:15
Data point term sent to Coder	System	07 Mar 2021 04:25:13
User entered 'gastritis'	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	16 Mar 2021 04:07:50
User entered 'No (N)'	Jessica Fisher (b) (4) [REDACTED]	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered 'No (N)'	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered '01 Feb 2021'	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered 'No (N)'	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered '0'	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered '0'	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered '0'	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	16 Mar 2021 04:07:50
User entered empty.	Jessica Fisher (b) (4) [REDACTED]	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	16 Mar 2021 04:07:50
User entered empty.	Jessica Fisher (b) (4) [REDACTED]	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered '0'	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	16 Mar 2021 04:07:50
User entered '0'	Jessica Fisher (b) (4) [REDACTED]	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered '0'	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered 'Not Related (NOT RELATED)'	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered 'Not Related (NOT RELATED)'	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered 'Not Applicable (NOT APPLICABLE)'	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

None

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered '0'	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered '1'	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered '0'	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:24:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Mar 2021 04:24:58

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:58:46
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 03:09:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 03:09:59
Data point term sent to Coder	System	24 Mar 2021 03:09:35
Coding entries removed.	Jessica Fisher (b) (4)	24 Mar 2021 03:09:16
Signature has been broken.	Jessica Fisher (b) (4)	24 Mar 2021 03:09:16
User entered 'WORSENING OF hypertension' reason for change: New Information	Jessica Fisher (b) (4)	24 Mar 2021 03:09:16
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Vascular tests NEC (incl blood pressure), PT: Blood pressure systolic increased, LLT: Blood pressure systolic increased - version MedDRA\\23.0.	Coder Import (b) (4)	07 Mar 2021 04:27:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Mar 2021 04:27:15
Data point term sent to Coder	System	07 Mar 2021 04:26:14
User entered 'worsening of systolic blood pressure'	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	16 Mar 2021 04:07:50
User entered 'No (N)'	Jessica Fisher (b) (4) [REDACTED]	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered 'No (N)'	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered '03 Mar 2021'	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered 'No (N)'	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered '0'	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered '0'	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered '0'	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	16 Mar 2021 04:07:50
User entered empty.	Jessica Fisher (b) (4) [REDACTED]	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	16 Mar 2021 04:07:50
User entered empty.	Jessica Fisher (b) (4) [REDACTED]	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	16 Mar 2021 04:07:50
User entered empty.	Jessica Fisher (b) (4) [REDACTED]	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered '0'	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered '0'	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered '0'	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered 'Not Related (NOT RELATED)'	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	16 Mar 2021 04:07:50
User entered 'Not Related (NOT RELATED)'	Jessica Fisher (b) (4) [REDACTED]	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered 'Dose Delayed (DOSE DELAYED)'	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

None

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered '0'	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered 'I'	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered '0'	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	16 Mar 2021 04:07:50
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:24:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Mar 2021 04:25:47

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Hypoaesthesia, LLT: Numbness of fingers - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 05:29:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 05:29:47
Data point term sent to Coder	System	22 Apr 2021 17:09:18
User entered 'Intermittent bilateral finger numbness'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '15 Mar 2021'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6) [REDACTED]	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6) [REDACTED]	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'I'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Apr 2021 17:08:58

US3162006

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:24:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Apr 2021 17:08:58

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:24:55

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:46:11
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:48:05

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:24:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 20:24:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 20:24:50
Data point term sent to Coder Coding entries removed.	System Cynthia Kunakom (b) (4)	04 Sep 2020 20:23:36 04 Sep 2020 20:23:01
User entered 'Hydrochlorothiazide' reason for change: Data Entry Error	Cynthia Kunakom (b) (4)	04 Sep 2020 20:23:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 02:50:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 02:50:10
Data point term sent to Coder User entered 'hydrochlorthiazide'	System Jared Bradshaw (b) (4)	06 Aug 2020 02:49:16 06 Aug 2020 02:48:54

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:48:54

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'hypertension'	Jared Bradshaw (b) (4)	06 Aug 2020 02:48:54

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '12.5'	Jared Bradshaw (b) (4)	06 Aug 2020 02:48:54

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'mg (mg)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:48:54

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:48:54

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'once daily (QD)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:48:54

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:24:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:48:54

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:48:54

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:24:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:48:54

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 09:36:43
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 02:48:54
User entered 'un Sep 2019'	Jared Bradshaw (b) (4)	06 Aug 2020 02:48:54

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Jared Bradshaw (b) (4)	06 Aug 2020 02:48:54

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 01:13:09
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:48:54

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '11 Nov 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 01:13:09
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:48:54

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:48:54

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:11
User entered '1'	System	06 Aug 2020 02:48:54

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:11
User entered '1'	System	06 Aug 2020 02:48:54

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:52:11
User entered '804 (804)'	System	06 Aug 2020 02:48:54

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 02:51:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 02:51:12
Data point term sent to Coder	System	06 Aug 2020 02:50:16
User entered 'losartan potassium'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 02:49:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:49:53
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'hypertension'	Jared Bradshaw (b) (4)	06 Aug 2020 02:49:53
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '100'	Jared Bradshaw (b) (4)	06 Aug 2020 02:49:53
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'mg (mg)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:49:53
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:49:53
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'once daily (QD)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:49:53
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:24:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:49:53
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:49:53
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:49:53
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 09:37:00
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 02:49:53
User entered 'un Oct 2017'	Jared Bradshaw (b) (4)	06 Aug 2020 02:49:53
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Jared Bradshaw (b) (4)	06 Aug 2020 02:49:53
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:49:53
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:49:53
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:49:53
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 02:49:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 02:49:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 02:49:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:24:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 02:52:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 02:52:01
Data point term sent to Coder	System	06 Aug 2020 02:51:17
User entered 'carvedilol'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 02:50:36

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:50:36
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'hypertension'	Jared Bradshaw (b) (4)	06 Aug 2020 02:50:36
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '6.25'	Jared Bradshaw (b) (4)	06 Aug 2020 02:50:36
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'mg (mg)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:50:36
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:50:36
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'twice daily (BID)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:50:36
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:24:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:50:36
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:50:36
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:50:36
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 09:37:12
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 02:50:36
User entered 'un UNK 2014'	Jared Bradshaw (b) (4)	06 Aug 2020 02:50:36
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Jared Bradshaw (b) (4)	06 Aug 2020 02:50:36
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:50:36
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:50:36
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:50:36
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Aug 2020 02:50:36

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 02:50:36

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 02:50:36

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 02:52:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 02:52:01
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 02:51:16
User entered 'rosuvastatin'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:06
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:06
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'hyperlipidemia'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:06
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '5'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:06
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'mg (mg)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:06
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:24:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:06
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'once daily (QD)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:06
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:24:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:06
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:06
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:06
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 09:37:24
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 02:51:06
User entered 'un UNK 2014'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:06
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:06
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:06
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:06
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:06
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 02:51:06

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 02:51:06

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 02:51:06

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 02:53:02
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 02:53:02
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 02:52:17
User entered 'gabapentin'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'restless leg syndrome'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '300'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'mg (mg)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'three times daily (TID)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:24:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 09:37:35
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 02:51:48
User entered 'un UNK 1990'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:51:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Aug 2020 02:51:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 02:51:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 02:51:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: ROPINIROLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 02:54:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 02:54:04
Data point term sent to Coder	System	06 Aug 2020 02:53:18
User entered 'ropinirole'	Jared Bradshaw (b) (4) (b) (4)	06 Aug 2020 02:52:28

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:52:28
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'restless leg syndrome'	Jared Bradshaw (b) (4)	06 Aug 2020 02:52:28
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '3'	Jared Bradshaw (b) (4)	06 Aug 2020 02:52:28
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'mg (mg)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:52:28
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:52:28
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'once daily (QD)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:52:28
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:24:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:52:28
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:52:28
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:52:28
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 09:37:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 02:52:28
User entered 'un UNK 2014'	Jared Bradshaw (b) (4)	06 Aug 2020 02:52:28
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Jared Bradshaw (b) (4)	06 Aug 2020 02:52:28
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:52:28
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:52:28
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:52:28
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 02:52:28

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 02:52:28

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 02:52:28

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 11:53:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 11:53:15
Data point term sent to Coder	System	06 Aug 2020 02:53:17
User entered 'venlafaxine'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:07
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:07
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'restless leg syndrome'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:07
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '37.5'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:07
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'mg (mg)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:07
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:07
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'once daily (QD)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:07
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:24:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:07
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:07
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:07
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 09:37:55
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 02:53:07
User entered 'un Apr 2018'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:07
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:07
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:07
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:07
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:07
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 02:53:07

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 02:53:07

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 02:53:07

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 02:55:07
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 02:55:07
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 02:54:18
User entered 'vitamin c'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'nutritional supplement'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '500'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'mg (mg)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:24:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'once daily (QD)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:24:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 09:38:05
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 02:53:48
User entered 'un UNK 2018'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:53:48
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 02:53:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 02:53:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 02:53:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 07:23:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 07:23:53
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 02:55:18
User entered 'aspirin'	Jared Bradshaw (b) (4)	06 Aug 2020 02:54:33
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:54:33
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'cardiac protection'	Jared Bradshaw (b) (4)	06 Aug 2020 02:54:33
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '81'	Jared Bradshaw (b) (4)	06 Aug 2020 02:54:33
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'mg (mg)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:54:33
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:54:33
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'once daily (QD)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:54:33
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:24:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:54:33
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:54:33
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:54:33
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 09:38:15
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 02:54:33
User entered 'un Sep 2019'	Jared Bradshaw (b) (4)	06 Aug 2020 02:54:33
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Jared Bradshaw (b) (4)	06 Aug 2020 02:54:33
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:54:33
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Jared Bradshaw (b) (4)	06 Aug 2020 02:54:33
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 02:54:33
	(b) (4)	

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 02:54:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 02:54:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 02:54:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:24:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:15
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: CODEINE PHOSPHATE;GUAIFENESIN, PRODUCTSYNONYM: VIRTUSSIN AC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 06:03:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 06:03:38
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
Data point term sent to Coder	System	13 Nov 2020 23:11:24
Coding entries removed.	Judith Kirstein (b) (4)	13 Nov 2020 23:11:21
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: CODEINE PHOSPHATE;GUAIFENESIN, PRODUCTSYNONYM: VIRTUSSIN AC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 04:21:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 04:21:38
Data point term sent to Coder	System	12 Nov 2020 17:13:21
User entered 'Virtussin AC (Codeine phosphate/ Guaifenesin)'	(b) (4), (b) (6)	12 Nov 2020 17:12:31

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:15
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 17:12:31

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:15
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'SYMPTOMATIC COVID-19' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 23:11:21
User entered 'acute viral infection, unspecified'	(b) (4), (b) (6)	12 Nov 2020 17:12:31

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:15
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '10/100'	(b) (4), (b) (6)	12 Nov 2020 17:12:31

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:15
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Nov 2020 17:12:31

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:15
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 17:12:31

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:15
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'once (ONCE)'	(b) (4), (b) (6)	12 Nov 2020 17:12:31

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:15
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 17:12:31

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:15
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Nov 2020 17:12:31

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:15
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 17:12:31

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:15
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '10 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 17:12:31

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:15
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 17:12:31

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:15
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 17:12:31

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:15
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '10 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 17:12:31

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:15
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 17:12:31

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:15
User entered empty.	System	12 Nov 2020 17:12:31

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:15
User entered empty.	System	12 Nov 2020 17:12:31

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:15
User entered empty.	System	12 Nov 2020 17:12:31

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
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)	13 Nov 2020 01:17:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 01:17:43
Data point term sent to Coder	System	13 Nov 2020 01:16:45
User entered 'FLU VACCINE'	Judith Kirstein (b) (4)	13 Nov 2020 01:15:59

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	13 Nov 2020 01:15:59

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'INFLUENZA PREVENTION'	Judith Kirstein (b) (4)	13 Nov 2020 01:15:59

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0.5'	Judith Kirstein (b) (4)	13 Nov 2020 01:15:59

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'mL (mL)'	Judith Kirstein (b) (4)	13 Nov 2020 01:15:59

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 01:15:59

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'once (ONCE)'	Judith Kirstein (b) (4)	13 Nov 2020 01:15:59

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 01:15:59

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Intramuscular (INTRAMUSCULAR)'	Judith Kirstein (b) (4)	13 Nov 2020 01:15:59

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 01:15:59

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '8 Oct 2020'	Judith Kirstein (b) (4)	13 Nov 2020 01:15:59

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Judith Kirstein (b) (4)	13 Nov 2020 01:15:59

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 01:15:59

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '8 Oct 2020'	Judith Kirstein (b) (4)	13 Nov 2020 01:15:59

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 01:15:59

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:19
User entered empty.	System	13 Nov 2020 01:15:59

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:19
User entered empty.	System	13 Nov 2020 01:15:59

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:19
User entered empty.	System	13 Nov 2020 01:15:59

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:30
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE RGE (CHO), PRODUCTSYNONYM: SHINGRIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 01:18:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 01:18:36
Data point term sent to Coder	System	13 Nov 2020 01:17:45
User entered 'SHINGRIX'	Judith Kirstein (b) (4)	13 Nov 2020 01:17:14

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:30
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	13 Nov 2020 01:17:14

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:30
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'SHINGLES PREVENTION'	Judith Kirstein (b) (4)	13 Nov 2020 01:17:14

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:30
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0.5'	Judith Kirstein (b) (4)	13 Nov 2020 01:17:14

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:30
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'mL (mL)'	Judith Kirstein (b) (4)	13 Nov 2020 01:17:14

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:30
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 01:17:14

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:30
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'once (ONCE)'	Judith Kirstein (b) (4)	13 Nov 2020 01:17:14

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:30
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 01:17:14

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:30
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Intramuscular (INTRAMUSCULAR)'	Judith Kirstein (b) (4)	13 Nov 2020 01:17:14

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:30
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 01:17:14

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:30
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '8 Oct 2020'	Judith Kirstein (b) (4)	13 Nov 2020 01:17:14

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:30
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Judith Kirstein (b) (4)	13 Nov 2020 01:17:14

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:30
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 01:17:14

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:30
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '8 Oct 2020'	Judith Kirstein (b) (4)	13 Nov 2020 01:17:14

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:30
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 01:17:14

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:30
User entered empty.	System	13 Nov 2020 01:17:14

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:30
User entered empty.	System	13 Nov 2020 01:17:14

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:30
User entered empty.	System	13 Nov 2020 01:17:14

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:24:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
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, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 05:15:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 05:15:41
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
Data point term sent to Coder	System	13 Nov 2020 23:24:42
User entered 'ROCEPHIN'	Judith Kirstein (b) (4)	13 Nov 2020 23:24:12

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:24:12

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'SYMPTOMATIC COVID-19'	Judith Kirstein (b) (4)	13 Nov 2020 23:24:12

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 23:51:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 23:51:30
User entered '1000' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 23:51:30
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 23:24:12
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:24:12

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'mg (mg)'	Judith Kirstein (b) (4)	13 Nov 2020 23:24:12

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:24:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:24:12

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'once (ONCE)'	Judith Kirstein (b) (4)	13 Nov 2020 23:24:12

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:24:12

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Intravenous (INTRAVENOUS)'	Judith Kirstein (b) (4)	13 Nov 2020 23:24:12

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:24:12

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 23:24:12

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Judith Kirstein (b) (4)	13 Nov 2020 23:24:12

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:24:12

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 23:24:12

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:41
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:24:12

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:41
User entered empty.	System	13 Nov 2020 23:24:12

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:41
User entered empty.	System	13 Nov 2020 23:24:12

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:41
User entered empty.	System	13 Nov 2020 23:24:12

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 23:52:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 23:52:38
Data point term sent to Coder	System	13 Nov 2020 23:52:12
Data point term sent to Coder	System	13 Nov 2020 23:25:43
User entered 'DEXAMETHASONE'	Judith Kirstein (b) (4)	13 Nov 2020 23:25:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:25:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'SYMPTOMATIC COVID-19'	Judith Kirstein (b) (4)	13 Nov 2020 23:25:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 23:52:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 23:52:02
User entered '6' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 23:52:02
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 23:25:29
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:25:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'mg (mg)'	Judith Kirstein (b) (4)	13 Nov 2020 23:25:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:25:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'once (ONCE)'	Judith Kirstein (b) (4)	13 Nov 2020 23:25:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:25:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 23:52:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 23:52:02
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 23:52:02
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 23:25:29
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:25:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:25:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 23:25:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Judith Kirstein (b) (4)	13 Nov 2020 23:25:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:25:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 23:25:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:25:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:51
User entered empty.	System	13 Nov 2020 23:25:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:51
User entered empty.	System	13 Nov 2020 23:25:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:51
User entered empty.	System	13 Nov 2020 23:25:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: ZITHROMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 05:04:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 05:04:42
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
Data point term sent to Coder	System	13 Nov 2020 23:51:11
Data point term sent to Coder	System	13 Nov 2020 23:27:46
User entered 'ZITHROMAX'	Judith Kirstein (b) (4)	13 Nov 2020 23:26:46

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:26:46

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'SYMPTOMATIC COVID-19'	Judith Kirstein (b) (4)	13 Nov 2020 23:26:46

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 23:50:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 23:50:54
User entered '500' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 23:50:54
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 23:26:46
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:26:46

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'mg (mg)'	Judith Kirstein (b) (4)	13 Nov 2020 23:26:46

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:24:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:26:46

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'once (ONCE)'	Judith Kirstein (b) (4)	13 Nov 2020 23:26:46

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:26:46

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 23:50:54
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 23:50:54
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 23:50:54
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 23:26:46
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:26:46

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:26:46

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 23:26:46

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Judith Kirstein (b) (4)	13 Nov 2020 23:26:46

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:26:46

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 23:26:46

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:26:46

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:58
User entered empty.	System	13 Nov 2020 23:26:46

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:58
User entered empty.	System	13 Nov 2020 23:26:46

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:53:58
User entered empty.	System	13 Nov 2020 23:26:46

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:05:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:05:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	12 Feb 2021 21:07:18
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:19:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Nov 2020 05:19:42
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
Data point term sent to Coder	System	13 Nov 2020 23:28:47
User entered 'NORMAL SALINE'	Judith Kirstein (b) (4) (b) (4)	13 Nov 2020 23:28:45

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:28:45

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 19:51:45
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' answered with 'Updated AE' (Site from DM).	Judith Kirstein (b) (4)	17 Dec 2020 21:53:59
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 07:11:37
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'ACUTE RENAL FAILURE'	Judith Kirstein (b) (4)	13 Nov 2020 23:28:45

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '1000'	Judith Kirstein (b) (4)	13 Nov 2020 23:28:45

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'mL (mL)'	Judith Kirstein (b) (4)	13 Nov 2020 23:28:45

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:28:45

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'once (ONCE)'	Judith Kirstein (b) (4)	13 Nov 2020 23:28:45

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:28:45

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Judith Kirstein (b) (4)	13 Nov 2020 23:28:45

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:28:45

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 23:28:45

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Judith Kirstein (b) (4)	13 Nov 2020 23:28:45

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:28:45

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 23:28:45

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:12
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:28:45

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:12
User entered empty.	System	13 Nov 2020 23:28:45

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:12
User entered empty.	System	13 Nov 2020 23:28:45

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:12
User entered empty.	System	13 Nov 2020 23:28:45

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 23:47:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 23:47:36
Data point term sent to Coder	System	13 Nov 2020 23:47:07
User entered 'VITAMIN C'	Judith Kirstein (b) (4)	13 Nov 2020 23:46:10

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:46:10

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'SYMPTOMATIC COVID-19'	Judith Kirstein (b) (4)	13 Nov 2020 23:46:10

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '1000'	Judith Kirstein (b) (4)	13 Nov 2020 23:46:10

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'mg (mg)'	Judith Kirstein (b) (4)	13 Nov 2020 23:46:10

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:46:10

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'other (OTHER)'	Judith Kirstein (b) (4)	13 Nov 2020 23:46:10

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'EVERY 12 HOURS'	Judith Kirstein (b) (4)	13 Nov 2020 23:46:10

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4)	13 Nov 2020 23:46:10

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:24:55

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:46:10

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 23:46:10

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Judith Kirstein (b) (4)	13 Nov 2020 23:46:10

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:46:10

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '12 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 23:46:10

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:19
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:46:10

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:19
User entered empty.	System	13 Nov 2020 23:46:10

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:19
User entered empty.	System	13 Nov 2020 23:46:10

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:19
User entered empty.	System	13 Nov 2020 23:46:10

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 23:48:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 23:48:37
Data point term sent to Coder	System	13 Nov 2020 23:48:08
User entered 'VITAMIN C'	Judith Kirstein (b) (4)	13 Nov 2020 23:47:44

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:47:44

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'SYMPTOMATIC COVID-19'	Judith Kirstein (b) (4)	13 Nov 2020 23:47:44

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '500'	Judith Kirstein (b) (4)	13 Nov 2020 23:47:44

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'mg (mg)'	Judith Kirstein (b) (4)	13 Nov 2020 23:47:44

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:47:44

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'once (ONCE)'	Judith Kirstein (b) (4)	13 Nov 2020 23:47:44

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:47:44

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4)	13 Nov 2020 23:47:44

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:47:44

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '12 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 23:47:44

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Judith Kirstein (b) (4)	13 Nov 2020 23:47:44

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:47:44

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '12 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 23:47:44

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:26
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:47:44

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:26
User entered empty.	System	13 Nov 2020 23:47:44

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:26
User entered empty.	System	13 Nov 2020 23:47:44

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:26
User entered empty.	System	13 Nov 2020 23:47:44

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: COLECALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 00:01:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 00:01:36
Data point term sent to Coder	System	14 Nov 2020 00:00:29
User entered 'COLECALCIFEROL'	Judith Kirstein (b) (4)	13 Nov 2020 23:59:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:59:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'SYMPTOMATIC COVID-19'	Judith Kirstein (b) (4)	13 Nov 2020 23:59:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '5000'	Judith Kirstein (b) (4)	13 Nov 2020 23:59:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'IU (IU)'	Judith Kirstein (b) (4)	13 Nov 2020 23:59:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:59:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'once daily (QD)'	Judith Kirstein (b) (4)	13 Nov 2020 23:59:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:59:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4)	13 Nov 2020 23:59:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 23:59:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 23:59:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Judith Kirstein (b) (4)	13 Nov 2020 23:59:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:59:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '12 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 23:59:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:38
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	13 Nov 2020 23:59:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:38
User entered '1'	System	13 Nov 2020 23:59:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:38
User entered '1'	System	13 Nov 2020 23:59:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:38
User entered '804 (804)'	System	13 Nov 2020 23:59:53

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:24:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:45
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Please verify if the following medications listed on hospital source be added into EDC: Carvedilol, meclizine, pantoprazole, ropinirole, thiamin, and venlafexine. Thank you.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 22:49:43
Query 'Please verify if the following medications listed on hospital source be added into EDC: Carvedilol, meclizine, pantoprazole, ropinirole, thiamin, and venlafexine. Thank you.' answered with 'See additions. ' (Site from CRA).	Judith Kirstein (b) (4)	16 Nov 2020 17:43:37
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User opened query 'Please verify if the following medications listed on hospital source be added into EDC: Carvedilol, meclizine, pantoprazole, ropinirole, thiamin, and venlafexine. Thank you.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 01:27:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Nov 2020 00:08:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Nov 2020 00:08:35
Data point term sent to Coder	System	14 Nov 2020 00:08:31
User entered 'HEPARIN'	Judith Kirstein (b) (4)	14 Nov 2020 00:07:32

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:45
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	14 Nov 2020 00:07:32

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:45
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'CLOT PREVENTION'	Judith Kirstein (b) (4)	14 Nov 2020 00:07:32

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:45
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '5000'	Judith Kirstein (b) (4)	14 Nov 2020 00:07:32

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:45
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'IU (IU)'	Judith Kirstein (b) (4)	14 Nov 2020 00:07:32

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:45
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 00:07:32

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:45
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'twice daily (BID)'	Judith Kirstein (b) (4)	14 Nov 2020 00:07:32

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:45
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 00:07:32

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:45
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Subcutaneous (SUBCUTANEOUS)'	Judith Kirstein (b) (4)	14 Nov 2020 00:07:32

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:45
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 00:07:32

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:45
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	14 Nov 2020 00:07:32

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:45
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Judith Kirstein (b) (4)	14 Nov 2020 00:07:32

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:45
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 00:07:32

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:45
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '12 Nov 2020'	Judith Kirstein (b) (4)	14 Nov 2020 00:07:32

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:45
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 00:07:32

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:45
User entered '2'	System	14 Nov 2020 00:07:32

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:45
User entered '1'	System	14 Nov 2020 00:07:32

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:45
User entered '804 (804)'	System	14 Nov 2020 00:07:32

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Subject received Oxygen Therapy for several hours, please update the con med source and EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 22:49:56
Query 'Subject received Oxygen Therapy for several hours, please update the con med source and EDC. Thank you.' answered with 'I have looked through the records again, and I don't see where she got oxygen. It was ordered when she went to the floor, but she refused it (it says refused in the records)' (Site from CRA).	Judith Kirstein (b) (4)	16 Nov 2020 17:44:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 05:04:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 05:04:42
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User opened query 'Subject received Oxygen Therapy for several hours, please update the con med source and EDC. Thank you.' (Site from CRA).	(b) (4), (b) (6)	14 Nov 2020 01:07:54
Data point term sent to Coder	System	14 Nov 2020 00:09:33
User entered 'ZINC SULFATE'	Judith Kirstein (b) (4)	14 Nov 2020 00:09:08

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 00:09:08

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'SYMPTOMATIC COVID-19'	Judith Kirstein (b) (4)	14 Nov 2020 00:09:08

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '220'	Judith Kirstein (b) (4)	14 Nov 2020 00:09:08

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'mg (mg)'	Judith Kirstein (b) (4)	14 Nov 2020 00:09:08

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 00:09:08

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'once daily (QD)'	Judith Kirstein (b) (4)	14 Nov 2020 00:09:08

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 00:09:08

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4)	14 Nov 2020 00:09:08

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 00:09:08

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	14 Nov 2020 00:09:08

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '0'	Judith Kirstein (b) (4)	14 Nov 2020 00:09:08

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 00:09:08

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered '12 Nov 2020'	Judith Kirstein (b) (4)	14 Nov 2020 00:09:08

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:58
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:28:11
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 00:09:08

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:58
User entered '1'	System	14 Nov 2020 00:09:08

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:58
User entered '1'	System	14 Nov 2020 00:09:08

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:54:58
User entered '804 (804)'	System	14 Nov 2020 00:09:08

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:03
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: THIAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 05:47:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 05:47:38
Data point term sent to Coder	System	14 Nov 2020 05:59:58
User entered 'THIAMINE'	Judith Kirstein (b) (4)	14 Nov 2020 05:59:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:03
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	14 Nov 2020 05:59:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:03
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'NUTRITIONAL SUPPLEMENT'	Judith Kirstein (b) (4)	14 Nov 2020 05:59:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:03
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered '100'	Judith Kirstein (b) (4)	14 Nov 2020 05:59:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:03
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'mg (mg)'	Judith Kirstein (b) (4)	14 Nov 2020 05:59:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:03
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 05:59:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:03
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'once daily (QD)'	Judith Kirstein (b) (4)	14 Nov 2020 05:59:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:03
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 05:59:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:03
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4)	14 Nov 2020 05:59:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:03
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 05:59:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:03
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	14 Nov 2020 05:59:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:03
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered '0'	Judith Kirstein (b) (4)	14 Nov 2020 05:59:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:03
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 05:59:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:03
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered '12 Nov 2020'	Judith Kirstein (b) (4)	14 Nov 2020 05:59:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:03
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 05:59:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:03
User entered '1'	System	14 Nov 2020 05:59:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:03
User entered '1'	System	14 Nov 2020 05:59:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:03
User entered '804 (804)'	System	14 Nov 2020 05:59:29

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:24:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:31
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: ANTIVERTIGO PREPARATIONS, ATC: ANTIVERTIGO PREPARATIONS, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 05:46:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 05:46:38
Data point term sent to Coder	System	14 Nov 2020 21:41:16
Coding entries removed.	Judith Kirstein (b) (4)	14 Nov 2020 21:40:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:02:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:02:47
Data point term sent to Coder	System	14 Nov 2020 06:01:58
User entered 'MECLIZINE'	Judith Kirstein (b) (4)	14 Nov 2020 06:01:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:31
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 06:01:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:31
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'LIGHTHEADEDNESS' reason for change: Data Entry Error	Judith Kirstein (b) (4)	14 Nov 2020 21:40:59
User entered 'VERTIGO'	Judith Kirstein (b) (4)	14 Nov 2020 06:01:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:31
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered '12.5'	Judith Kirstein (b) (4)	14 Nov 2020 06:01:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:31
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'mg (mg)'	Judith Kirstein (b) (4)	14 Nov 2020 06:01:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:31
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:01:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:31
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'once (ONCE)'	Judith Kirstein (b) (4)	14 Nov 2020 06:01:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:31
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:01:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:31
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4)	14 Nov 2020 06:01:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:31
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered empty.	Judith Kirstein (b) (4)	14 Nov 2020 06:01:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:31
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	14 Nov 2020 06:01:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:31
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered '0'	Judith Kirstein (b) (4)	14 Nov 2020 06:01:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:31
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 06:01:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:31
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	14 Nov 2020 06:01:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:31
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'No (N)'	Judith Kirstein (b) (4)	14 Nov 2020 06:01:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:31
User entered empty.	System	14 Nov 2020 06:01:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:31
User entered empty.	System	14 Nov 2020 06:01:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:31
User entered empty.	System	14 Nov 2020 06:01:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
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)	16 Nov 2020 20:21:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Nov 2020 20:21:47
Data point term sent to Coder	System	16 Nov 2020 20:21:03
User entered 'PANTOPRAZOLE'	Judith Kirstein (b) (4)	16 Nov 2020 20:20:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'No (N)'	Judith Kirstein (b) (4)	16 Nov 2020 20:20:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'GASTRITIS'	Judith Kirstein (b) (4)	16 Nov 2020 20:20:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered '40'	Judith Kirstein (b) (4)	16 Nov 2020 20:20:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'mg (mg)'	Judith Kirstein (b) (4)	16 Nov 2020 20:20:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered empty.	Judith Kirstein (b) (4)	16 Nov 2020 20:20:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'once daily (QD)'	Judith Kirstein (b) (4)	16 Nov 2020 20:20:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered empty.	Judith Kirstein (b) (4)	16 Nov 2020 20:20:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4)	16 Nov 2020 20:20:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered empty.	Judith Kirstein (b) (4)	16 Nov 2020 20:20:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'UN UNK 2019'	Judith Kirstein (b) (4)	16 Nov 2020 20:20:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered '0'	Judith Kirstein (b) (4)	16 Nov 2020 20:20:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 19:21:08
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	16 Nov 2020 20:20:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered '17 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	19 Nov 2020 19:21:08
User entered empty.	Judith Kirstein (b) (4)	16 Nov 2020 20:20:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:47
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'No (N)'	Judith Kirstein (b) (4)	16 Nov 2020 20:20:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:47
User entered '1'	System	16 Nov 2020 20:20:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:47
User entered '1'	System	16 Nov 2020 20:20:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:47
User entered '804 (804)'	System	16 Nov 2020 20:20:33

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:24:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User closed query 'Line 26 and 27 in eSource (Zinc/Vitamin C and Tylenol extra strength) have been added. Please update EDC with these two con meds. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 22:22:06
Query 'Line 26 and 27 in eSource (Zinc/Vitamin C and Tylenol extra strength) have been added. Please update EDC with these two con meds. Thank you.' answered with 'Tylenol has been corrected in source and EDC. Zinc/Vit C was not related to MAAE. Was to prevent it in future. So would not go in EDC.' (Site from CRA).	Judith Kirstein (b) (4)	10 Dec 2020 21:37:58
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User opened query 'Line 26 and 27 in eSource (Zinc/Vitamin C and Tylenol extra strength) have been added. Please update EDC with these two con meds. Thank you.' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 20:09:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Nov 2020 19:46:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Nov 2020 19:46:02
Data point term sent to Coder	System	19 Nov 2020 19:45:23
User entered 'acetaminophen'	Judith Kirstein (b) (4)	19 Nov 2020 19:45:00

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'No (N)'	Judith Kirstein (b) (4)	19 Nov 2020 19:45:00

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'Symptomatic Covid-19'	Judith Kirstein (b) (4)	19 Nov 2020 19:45:00

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered '500'	Judith Kirstein (b) (4)	19 Nov 2020 19:45:00

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'mg (mg)'	Judith Kirstein (b) (4)	19 Nov 2020 19:45:00

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered empty.	Judith Kirstein (b) (4)	19 Nov 2020 19:45:00

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'as needed (PRN)'	Judith Kirstein (b) (4)	19 Nov 2020 19:45:00

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered empty.	Judith Kirstein (b) (4)	19 Nov 2020 19:45:00

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4)	19 Nov 2020 19:45:00

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered empty.	Judith Kirstein (b) (4)	19 Nov 2020 19:45:00

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered '12 Nov 2020'	Judith Kirstein (b) (4)	19 Nov 2020 19:45:00

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered '0'	Judith Kirstein (b) (4)	19 Nov 2020 19:45:00

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 22:23:29
User closed query 'Per eSource, a stop date of 19 Nov 2020 has been updated. Please update EDC. Thank you. (ensure the stop dat is noted in the question below). Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 22:23:26
Query 'Per eSource, a stop date of 19 Nov 2020 has been updated. Please update EDC. Thank you. (ensure the stop dat is noted in the question below). Thank you.' answered with 'Correct in source and EDC' (Site from CRA).	Judith Kirstein (b) (4)	10 Dec 2020 21:38:17
DataPoint Un-verified.	Judith Kirstein (b) (4)	10 Dec 2020 21:36:53
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	10 Dec 2020 21:36:53
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User opened query 'Per eSource, a stop date of 19 Nov 2020 has been updated. Please update EDC. Thank you. (ensure the stop dat is noted in the question below). Thank you.' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 20:02:30
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	19 Nov 2020 19:45:00

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 22:23:31
DataPoint Un-verified.	Judith Kirstein (b) (4)	10 Dec 2020 21:36:53
User entered '19 Nov 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	10 Dec 2020 21:36:53
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered empty.	Judith Kirstein (b) (4)	19 Nov 2020 19:45:00

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:51
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 20:09:20
User entered 'No (N)'	Judith Kirstein (b) (4)	19 Nov 2020 19:45:00

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:51
User entered empty.	System	19 Nov 2020 19:45:00

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:51
User entered empty.	System	19 Nov 2020 19:45:00

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:55:51
User entered empty.	System	19 Nov 2020 19:45:00

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:24:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), COMBINATIONS, PRODUCT: ASCORBIC ACID;ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 17:58:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 17:58:55
Data point term sent to Coder	System	15 Jan 2021 05:20:20
User entered 'zinc/vitamin c (garden of life)'	Jessica Fisher (b) (4)	15 Jan 2021 05:19:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	15 Jan 2021 05:19:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'covid prevention'	Jessica Fisher (b) (4)	15 Jan 2021 05:19:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '30/60'	Jessica Fisher (b) (4)	15 Jan 2021 05:19:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'mg (mg)'	Jessica Fisher (b) (4)	15 Jan 2021 05:19:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jessica Fisher (b) (4)	15 Jan 2021 05:19:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'once daily (QD)'	Jessica Fisher (b) (4)	15 Jan 2021 05:19:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jessica Fisher (b) (4)	15 Jan 2021 05:19:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Oral (ORAL)'	Jessica Fisher (b) (4)	15 Jan 2021 05:19:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jessica Fisher (b) (4)	15 Jan 2021 05:19:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '21 Nov 2020'	Jessica Fisher (b) (4)	15 Jan 2021 05:19:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:24:55

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jessica Fisher (b) (4)	15 Jan 2021 05:19:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	15 Jan 2021 05:19:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jessica Fisher (b) (4)	15 Jan 2021 05:19:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jessica Fisher (b) (4)	15 Jan 2021 05:19:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 05:19:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Jan 2021 05:19:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Jan 2021 05:19:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL EXTRA STRENGTH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 05:22:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Jan 2021 05:22:03
Data point term sent to Coder	System	15 Jan 2021 05:21:20
User entered 'Tylenol extra strength'	Jessica Fisher (b) (4)	15 Jan 2021 05:20:37

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jessica Fisher (b) (4)	15 Jan 2021 05:20:37

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'symptomatic covid-19'	Jessica Fisher (b) (4)	15 Jan 2021 05:20:37

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '500'	Jessica Fisher (b) (4)	15 Jan 2021 05:20:37

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'mg (mg)'	Jessica Fisher (b) (4)	15 Jan 2021 05:20:37

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jessica Fisher (b) (4)	15 Jan 2021 05:20:37

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'as needed (PRN)'	Jessica Fisher (b) (4)	15 Jan 2021 05:20:37

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jessica Fisher (b) (4)	15 Jan 2021 05:20:37

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'Oral (ORAL)'	Jessica Fisher (b) (4)	15 Jan 2021 05:20:37

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered empty.	Jessica Fisher (b) (4)	15 Jan 2021 05:20:37

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '12 Nov 2020'	Jessica Fisher (b) (4)	15 Jan 2021 05:20:37

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '0'	Jessica Fisher (b) (4)	15 Jan 2021 05:20:37

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jessica Fisher (b) (4)	15 Jan 2021 05:20:37

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '12 Nov 2020'	Jessica Fisher (b) (4)	15 Jan 2021 05:20:37

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:07
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered 'No (N)'	Jessica Fisher (b) (4)	15 Jan 2021 05:20:37

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:07
User entered empty.	System	15 Jan 2021 05:20:37

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:07
User entered empty.	System	15 Jan 2021 05:20:37

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:07
User entered empty.	System	15 Jan 2021 05:20:37

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:24:55

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
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)	07 Mar 2021 04:27:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Mar 2021 04:27:16
Data point term sent to Coder	System	07 Mar 2021 04:27:14
User entered 'pantoprazole'	Jessica Fisher (b) (4)	07 Mar 2021 04:26:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'No (N)'	Jessica Fisher (b) (4)	07 Mar 2021 04:26:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'gastritis'	Jessica Fisher (b) (4)	07 Mar 2021 04:26:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered '40'	Jessica Fisher (b) (4)	07 Mar 2021 04:26:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'mg (mg)'	Jessica Fisher (b) (4)	07 Mar 2021 04:26:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:26:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'once daily (QD)'	Jessica Fisher (b) (4)	07 Mar 2021 04:26:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:26:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'Oral (ORAL)'	Jessica Fisher (b) (4)	07 Mar 2021 04:26:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:26:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered '04 Mar 2021'	Jessica Fisher (b) (4)	07 Mar 2021 04:26:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered '0'	Jessica Fisher (b) (4)	07 Mar 2021 04:26:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	07 Mar 2021 04:26:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:26:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'No (N)'	Jessica Fisher (b) (4)	07 Mar 2021 04:26:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Mar 2021 04:26:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Mar 2021 04:26:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Mar 2021 04:26:49

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:24:55

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, CENTRALLY ACTING, ATC: IMIDAZOLINE RECEPTOR AGONISTS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Mar 2021 04:29:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Mar 2021 04:29:15
Data point term sent to Coder User entered 'clonidine'	System Jessica Fisher (b) (4)	07 Mar 2021 04:28:15 07 Mar 2021 04:27:26

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'No (N)'	Jessica Fisher (b) (4)	07 Mar 2021 04:27:26

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'worsening of hypertension'	Jessica Fisher (b) (4)	07 Mar 2021 04:27:26

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered '0.1'	Jessica Fisher (b) (4)	07 Mar 2021 04:27:26

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'mg (mg)'	Jessica Fisher (b) (4)	07 Mar 2021 04:27:26

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:27:26

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'once (ONCE)'	Jessica Fisher (b) (4)	07 Mar 2021 04:27:26

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:27:26

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'Oral (ORAL)'	Jessica Fisher (b) (4)	07 Mar 2021 04:27:26

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:27:26

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered '03 Mar 2021'	Jessica Fisher (b) (4)	07 Mar 2021 04:27:26

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered '0'	Jessica Fisher (b) (4)	07 Mar 2021 04:27:26

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'No (N)'	Jessica Fisher (b) (4)	07 Mar 2021 04:27:26

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered '03 Mar 2021'	Jessica Fisher (b) (4)	07 Mar 2021 04:27:26

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'No (N)'	Jessica Fisher (b) (4)	07 Mar 2021 04:27:26

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:16
User entered empty.	System	07 Mar 2021 04:27:26

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:16
User entered empty.	System	07 Mar 2021 04:27:26

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:16
User entered empty.	System	07 Mar 2021 04:27:26

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:21
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: CAPTOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:56:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:56:55
Data point term sent to Coder	System	07 Mar 2021 04:28:15
User entered 'captopril'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:01

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:21
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'No (N)'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:01

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:21
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'worsening of hypertension'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:01

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:21
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered '25'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:01

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:21
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'mg (mg)'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:01

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:21
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:28:01

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:21
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'once (ONCE)'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:01

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:24:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:21
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:28:01

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:21
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'Oral (ORAL)'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:01

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:21
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:28:01

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:24:55

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:21
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered '03 Mar 2021'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:01

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:21
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered '0'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:01

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:21
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'No (N)'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:01

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:21
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered '03 Mar 2021'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:01

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:21
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'No (N)'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:01

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:21
User entered empty.	System	07 Mar 2021 04:28:01

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:21
User entered empty.	System	07 Mar 2021 04:28:01

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:56:21
User entered empty.	System	07 Mar 2021 04:28:01

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE, PRODUCTSYNONYM: TRIAMTERENE/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Mar 2021 04:30:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Mar 2021 04:30:15
Data point term sent to Coder	System	07 Mar 2021 04:29:15
User entered 'triamterene/hydrochlorothiazide'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'No (N)'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'worsening of hypertension'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered '37.5/25'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'mg (mg)'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:28:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'once daily (QD)'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:24:55

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered empty.	Jessica Fisher (b) (4)	07 Mar 2021 04:28:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'Oral (ORAL)'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	08 Apr 2021 21:22:43
User entered empty.	Jessica Fisher (b) (4) [REDACTED]	07 Mar 2021 04:28:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered '04 Mar 2021'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:24:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered '0'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'Yes (Y)'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	08 Apr 2021 21:22:43
User entered empty.	Jessica Fisher (b) (4) [REDACTED]	07 Mar 2021 04:28:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:22:43
User entered 'No (N)'	Jessica Fisher (b) (4)	07 Mar 2021 04:28:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Mar 2021 04:28:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Mar 2021 04:28:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Mar 2021 04:28:48

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:24:55

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: DIURETICS AND POTASSIUM-SPARING AGENTS IN COMBINATION, ATC: LOW-CEILING DIURETICS AND POTASSIUM-SPARING AGENTS, PRODUCT: HYDROCHLOROTHIAZIDE;TRIAMTERENE, PRODUCTSYNONYM: TRIAMTERENE/HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 17:07:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 17:07:54
Data point term sent to Coder	System	22 Apr 2021 17:07:17
User entered 'Triamterene/Hydrochlorothiazide'	(b) (4), (b) (6)	22 Apr 2021 17:06:34

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:24:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 17:06:34

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Hypertension'	(b) (4), (b) (6)	22 Apr 2021 17:06:34

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:24:55

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '37.5/25'	(b) (4), (b) (6)	22 Apr 2021 17:06:34

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:24:55

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'mg (mg)'	(b) (4), (b) (6)	22 Apr 2021 17:06:34

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:24:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:06:34

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:24:55

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'once daily (QD)'	(b) (4), (b) (6)	22 Apr 2021 17:06:34

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:24:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:06:34

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:24:55

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	22 Apr 2021 17:06:34

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:24:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:06:34

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:24:55

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '12 Mar 2021'	(b) (4), (b) (6)	22 Apr 2021 17:06:34

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:24:55

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '0'	(b) (4), (b) (6)	22 Apr 2021 17:06:34

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:24:55

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Apr 2021 17:06:34

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:24:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:06:34

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:24:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'No (N)'	(b) (4), (b) (6)	22 Apr 2021 17:06:34

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:24:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 17:06:34

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 17:06:34

US3162006

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:24:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Apr 2021 17:06:34

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:24:55

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:11
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 00:54:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	13 Nov 2020 21:05:47
User entered 'No (N)'	Jared Bradshaw (b) (4)	06 Aug 2020 19:19:51

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:24:55

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	14 Nov 2020 01:33:38
User entered '11 Nov 2020'	Judith Kirstein (b) (4) [REDACTED] [REDACTED]	13 Nov 2020 21:06:27

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:24:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) [REDACTED]	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	14 Nov 2020 01:33:38
User entered 'Portable chest xray'	Judith Kirstein (b) (4) [REDACTED] [REDACTED]	13 Nov 2020 21:06:27

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:38
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4)	13 Nov 2020 21:06:27

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:24:55

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:38
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 21:06:27

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:24:55

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:50
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:38
User entered '12 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 21:07:10

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:24:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:50
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:38
User entered 'Single view chest xray'	Judith Kirstein (b) (4)	13 Nov 2020 21:07:10

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:50
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:38
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4)	13 Nov 2020 21:07:10

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:24:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:50
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:38
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 21:07:10

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:24:55

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:38
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 21:07:58

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:24:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:38
User entered 'CT scan of head without contrast'	Judith Kirstein (b) (4)	13 Nov 2020 21:07:58

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:38
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4)	13 Nov 2020 21:07:58

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:24:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:52
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:38
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 21:07:58

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:24:55

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:54
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:38
User entered '11 Nov 2020'	Judith Kirstein (b) (4)	13 Nov 2020 21:09:08

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:24:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:54
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:38
User entered 'Renal ultrasound'	Judith Kirstein (b) (4)	13 Nov 2020 21:09:08

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:54
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:38
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4)	13 Nov 2020 21:09:08

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:24:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:54
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	14 Nov 2020 01:33:38
User entered empty.	Judith Kirstein (b) (4)	13 Nov 2020 21:09:08

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:24:55

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:58
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered '11 Nov 2020'	(b) (4), (b) (6)	22 Apr 2021 17:07:17

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:24:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:58
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Electrocardiogram'	(b) (4), (b) (6)	22 Apr 2021 17:07:17

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:24:55

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:58
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	22 Apr 2021 17:07:17

US3162006

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:24:55

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:21:58
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 16:53:19
User entered empty.	(b) (4), (b) (6)	22 Apr 2021 17:07:17

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered	System	13 Nov 2020 15:33:23
'USA-US074-2020-MRNA-1273-P301000008'		

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Yes (Y)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Yes (Y)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Judith'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Kirstein'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'BANNING'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'CA'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered '92220'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'US'	System	13 Nov 2020 15:33:42

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '5'	System	18 Dec 2020 18:30:29
User entered '4'	System	30 Nov 2020 14:41:27
User entered '3'	System	20 Nov 2020 23:01:13
User entered '2'	System	16 Nov 2020 13:40:58
User entered '1'	System	13 Nov 2020 15:33:42

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered	System	13 Nov 2020 15:33:23
'USA-US074-2020-MRNA-1273-P301000008'		

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Yes (Y)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Yes (Y)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Judith'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Kirstein'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'BANNING'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'CA'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered '92220'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'US'	System	13 Nov 2020 15:33:42

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '5'	System	18 Dec 2020 18:30:29
User entered '4'	System	30 Nov 2020 14:41:27
User entered '3'	System	20 Nov 2020 23:01:13
User entered '2'	System	16 Nov 2020 13:40:58
User entered '1'	System	13 Nov 2020 15:33:42

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:24:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
User entered '13/Nov/2020 10:33'	System	13 Nov 2020 15:33:42

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:24:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 15:33:42

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered	System	13 Nov 2020 15:33:23
'USA-US074-2020-MRNA-1273-P301000008'		

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Yes (Y)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Yes (Y)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Judith'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Kirstein'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'BANNING'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'CA'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered '92220'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'US'	System	13 Nov 2020 15:33:42

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '5'	System	18 Dec 2020 18:30:29
User entered '4'	System	30 Nov 2020 14:41:27
User entered '3'	System	20 Nov 2020 23:01:13
User entered '2'	System	16 Nov 2020 13:40:58
User entered '1'	System	13 Nov 2020 15:33:42

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:24:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
User entered '16/Nov/2020 13:40'	System	16 Nov 2020 13:40:58

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:24:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:41:17
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 13:40:58

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered	System	13 Nov 2020 15:33:23
'USA-US074-2020-MRNA-1273-P301000008'		

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Yes (Y)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Yes (Y)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Judith'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Kirstein'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'BANNING'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'CA'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered '92220'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'US'	System	13 Nov 2020 15:33:42

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '5'	System	18 Dec 2020 18:30:29
User entered '4'	System	30 Nov 2020 14:41:27
User entered '3'	System	20 Nov 2020 23:01:13
User entered '2'	System	16 Nov 2020 13:40:58
User entered '1'	System	13 Nov 2020 15:33:42

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:24:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
User entered '20/Nov/2020 18:01'	System	20 Nov 2020 23:01:13

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:24:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 14:41:17
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
User entered 'I'	(b) (4), (b) (6)	20 Nov 2020 23:01:13

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'USA-US074-2020-MRNA-1273-P301000008'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Yes (Y)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Yes (Y)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Judith'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Kirstein'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'BANNING'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'CA'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered '92220'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'US'	System	13 Nov 2020 15:33:42

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '5'	System	18 Dec 2020 18:30:29
User entered '4'	System	30 Nov 2020 14:41:27
User entered '3'	System	20 Nov 2020 23:01:13
User entered '2'	System	16 Nov 2020 13:40:58
User entered '1'	System	13 Nov 2020 15:33:42

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:24:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:57:45
User entered '30/Nov/2020 14:41'	System	30 Nov 2020 14:41:27

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:24:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 18:30:13
DataPoint Verified.	(b) (4), (b) (6)	09 Dec 2020 19:57:48
User entered 'I'	(b) (4), (b) (6)	30 Nov 2020 14:41:27

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered	System	13 Nov 2020 15:33:23
'USA-US074-2020-MRNA-1273-P301000008'		

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Yes (Y)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

Death

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Yes (Y)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'No (N)'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Judith'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'Kirstein'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'BANNING'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'CA'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered '92220'	System	13 Nov 2020 15:33:23

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 13:40:38
User entered 'US'	System	13 Nov 2020 15:33:42

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:24:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
User entered '5'	System	18 Dec 2020 18:30:29
User entered '4'	System	30 Nov 2020 14:41:27
User entered '3'	System	20 Nov 2020 23:01:13
User entered '2'	System	16 Nov 2020 13:40:58
User entered '1'	System	13 Nov 2020 15:33:42

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:24:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:07:41
User entered '18/Dec/2020 10:30'	System	18 Dec 2020 18:30:29

US3162006

Folder: SAE USA-US074-2020-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:24:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	12 Feb 2021 21:07:18
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 20:07:43
User entered 'I'	(b) (4), (b) (6)	18 Dec 2020 18:30:29